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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Gad	Terliuc	Raanana, Israel

☐ *Additional inventors are being named on the* --- *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Devices, accessories and methods for endoscopy and in-pipe propagation

CORRESPONDENCE ADDRESS

Direct all correspondence to:

☐ Customer Number [ ] *Type Customer Number here* → *Place Customer Number Bar Code Label here*

OR

☑ Firm *or* Individual Name	Gad Terliuc				
Address	12 Macabi street				
Address					
City	Raanana	State		ZIP	43254
Country	Israel	Telephone	972-9-7441919	Fax	—

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METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

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Respectfully submitted,

SIGNATURE [signature]

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TYPED or PRINTED NAME Gad Terliuc

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

Wednesday, March 24th, 2004
Title: **Devices, accessories and methods for endoscopy and in-pipe propagation.**
Inventor: Gad Terliuc
This is a provisional application for a US patent.

FIELD OF THE INVENTION

The invention relates to devices, means and methods for progressing in the interior of a tubular pipe, and to related accessories. More specifically, it relates to devices, means and methods and related accessories for progressing in the interior of a tubular pipe of varying cross-section and diameter, having straight and curved portions and tight bends, and of flexible and stretchable walls. Particularly, it relates to devices, means and methods and accessories for inspecting, examining and treating the interior of human or animals' tubular cavities and canals. More particularly, it relates to devices, means, methods and accessories for performing endoscopy, colonoscopy or gastroscopy. An aspect of the present invention relates to a micro-robot with self-locomotion capabilities (hereinafter also denoted "MR") for in-pipe progressing and to related accessories. Yet an aspect of the present invention relates to devices, methods and accessories for in-pipe progressing, utilizing two flexible tubes, inserted one within the other and having different properties, which progress in conjugation, alternately.

INTRODUCTION

The provisional application for a US patent by Gad Terliuc, filed in February 2004, entitled "**Improved micro-robot and accessories for endoscopy and in-pipe locomotion**", is included in its entirety. It is denoted and referred to at the following as "*the former application*".

Many drawbacks of conventional gastrointestinal (GI) endoscopy, e.g., colonoscopy and gastroscopy, were detailed in *the former application*. Limited maneuvering and steering ability, difficulty to progress through tight bends of the intestine, non-coverage of most of the small intestine, chances to perforate the intestinal walls, and other deficiencies, have led to search for alternative methods for endoscopic procedures, such as endoscopy micro-robots (MR) that progress through the interior of the intestine by their own locomotion, while utilizing gripping (namely clamping) of the inner intestinal walls.

Such endoscopy MR and accessories are a major aspect of *the former application*, and are described in details therein.
Accordingly, an object of the present invention is to afford some variations, modifications and specific uses of MR such as the MR of *the former application*.

Thus, a first aspect of the present invention is to afford a variation and an improved functionality of a MR (e.g., such as the one described in *the former application*). Conventional flexible endoscopes (for example the colonoscopes made by OLYMPUS Optics Co, Japan), afford a controlled bending of the colonoscope's head, such as a left-right and up-down bending. This is used for searching and finding the way through the intestine (mostly in a bent or non-inflated area) and for closely inspecting the internal sidewalls of the intestine. This functionality is beneficial also for an endoscope MR. Thus; an aspect of the invention is to afford either bending or tilting of the MR with respect to the intestine's walls and longitudinal axis. Furthermore, the present invention MR affords high control level and accurate positioning of the MR head with respect to the intestinal wall, which is not achievable either by conventional endoscopes or by prior art MR. In conventional flexible endoscopes (e.g., as in push-colonoscopy) there is limited control of the approaching angle of the endoscope and pass-through accessories towards the intestinal wall to be inspected or treated. It is difficult to control the position and angle of the colonoscope's head within the intestine, since the head's positioning within the intestine is facilitated through pulling, pushing and/or rotating the colonoscope's tail out of the body, a long distance from the head. The head's bending gives only a partial control over the head's positioning and the accessory's approach angle toward the intestine's treated point. An example consequence of this deficiency is that some of the polyps inspected during colonoscopy cannot be accessed and removed by the accessory (e.g., wire cutter, biopsy arm, tweezers, etc) due to inappropriate access angle and positioning of the accessory towards the polyp. This implies a full-scale surgery if the polyp is cancerous, a surgery that could have been avoided if the accessory was able to access the polyp and remove it. Prior art endoscopy MR also fail to afford a sufficient degree of control over the approach angle and vicinity of the MR head or accessory with respect to the intestine's examined or treated point (e.g., a polyp). Such endoscopy MR are primarily designed to propagate forward or backward in the intestine, not to change their angle relative to the intestine's longitudinal axis. In a sense, prior art MR might be even more limited in their approach angle and positioning than conventional push-endoscopes.

The present invention MR addresses this issue, and affords a controllable, tunable and accurate approaching angle and positioning of the MR head and the accessory passed through the MR, with respect to the intestinal wall and any specific point within the intestinal wall. The present invention MR can change the angle between its main (longitudinal) axis and the intestine's longitudinal axis, thereby affording any approach-angle towards a desired point within the intestinal internal wall. Independently, the invention MR can be tuned to be either centered with respect to the intestine (namely a position in which the MR and the intestine are concentric, having their longitudinal axes coincide), or non-centered (namely a position in which the MR and the intestine are non-concentric), in-which case the MR main axis is closer to one intestinal wall and farther from its counter wall (namely asymmetrically positioned). These two positioning controls can be set independently and continuously, thereby affording the desired positioning and angle control.

Another aspect of the present invention relates to improved progressing and maneuverability of a flexible endoscope during push-endoscopy or the like. It specifically concerns a long flexible endoscope that has to traverse a long distance within a long and highly bent tubular organ of a large cross-section diameter, like the colon or the small intestine. In conventional push-endoscopy of such organs, the endoscope (e.g., colonoscope, gastroscope) is flexible but yet massive and has a large diameter (e.g., typical colonoscopes' diameter is over 1 centimeter), and exhibits a considerable bending-resistance. This is because the pushing action of the endoscope's tail into the body's opening (e.g., the anus) should be carried (namely passed-on) by the endoscope's body, through all of its length and through its curved trajectory, till it reaches and advances the endoscope's head. A very flexible and highly bendable endoscope would fail to traverse a long distance within the organ, and would probably be bent and get stuck close to the beginning of the organ, in one of the early bends (namely bends closer to the opening).

However, this semi-rigidity (namely less-flexibility) of the endoscope has drawbacks, because the pushing action of a less flexible, more rigid endoscope exerts high forces on the inspected organ, and because it is very difficult for such an endoscope to traverse tight bends (as is frequently the case in gastrointestinal endoscopy). There is thus a tradeoff between flexibility and rigidity of conventional flexible endoscopes. This tradeoff results in non-ideal flexible endoscopes, which exert forces on the intestine and have difficulty to propagate through tight bends, while still are difficult to push-through and maneuver a long distance.

It is thus an object of the present invention to afford a method and related devices or accessories for assisting the insertion, maneuvering and progressing of an endoscope, catheter or the like within a duct (e.g., a tubular organ such as the colon, the small intestine, the coronary system, arteries or veins, or the like), and especially within a long duct having many curves and tight bends. This method, to be described in detailed in the next sections, is based upon two flexible tubes, one inserted within the other, having different properties (e.g., mechanical properties such as flexibility, bending-strength, friction with the duct's interior, etc), which are propagating in conjugation, alternately.

The former application also describes a device for performing sampling of the internal walls of the intestine (e.g., the colon) or another tubular organ, a sampling that could be performed prior to an endoscopy, in addition to endoscopy, or without any relation to endoscopy. Accordingly, an aspect of the present invention is to afford a specific variation and usage for such a sampling device.

SUMMARY OF THE INVENTION

It is appreciated that the description of the invention hereinafter will mainly focus on endoscopy of the gastrointestinal system, but the scope of the invention is not limited to this organ and some or all of the described methods, concepts, apparatuses, systems, notions and so, may be applicable to endoscopy and sampling of other organic ducts (as

well as to propagation within inorganic tubular systems, and their inspection, sampling and treatment); a specific application to be described at the following is of gynecological sampling taken from a feminine tubular organ (e.g., vagina, cervix), applying the concept of the sampling accessory of *the former application*.
Moreover, they could be applicable also to other fields in which a MR is to propagate through a tubular duct, and particularly to examine, inspect or treat the internal surface of this duct. Such fields may include the internal inspection and fixing of industrial pipes for chemicals transport, installation pipes, applications where a cable or wire should be transferred through a pipe (electricity, phone or communication cables etc) and hence using the MR as a locomotive carrier or using the two tubes apparatus for assisting in-pipe cable or wire transport, and more. A specific application to be described at the following is of a locomotive rock-driller for uses such as oil searching, which affords a curved drilling path.

A first aspect of the present invention is to afford a variation and an improved functionality, maneuverability, positioning and approaching angle of a MR.
Relating to the MR with the inflatable-balloon clamping-units of *the former application*, a MR of the present invention comprises few balloon segments in each clamping unit (the front and rear) or in one of them, altogether constructing the ring-shaped clamping unit. Each segment of the clamping unit could be inflated or deflated separately, by conventional means such as a separate pneumatic tube, connected to or disconnected from the pneumatic line (e.g., the flexible tubular duct of the rear bundle) by suitable openings and control of the tail's valve, as described in details in *the former application*. Each balloon segment could be fully inflated, partially inflated, or not inflated at all, as needed. The inflation/deflation mechanism, mechanics and control, resemble that of the MR of *the former application*. Partial inflation could be facilitated through connecting the relevant tube for a short time, or through an appropriate pressure in the pneumatic line, which is lower than the pressure used for full inflation. Thus, the degree of inflation of each segment could be controlled continuously (between full deflation and full inflation) and separately. In-parallel (namely simultaneous) inflation and deflation of few balloons' segments could be facilitated, for example by incorporating more than one pneumatic valve for the clamping units' segments inflation/deflation.
Different amount of inflation of the various balloons' segments consequences in different positioning of the MR with respect to the intestine, in terms of both angle and asymmetric vicinity to the intestinal walls, as demonstrated by the various embodiments and examples in the detailed description bellow.

As mentioned in the introduction, another object of the present invention is to afford improved progressing and maneuverability of a flexible push-endoscope or any other long, flexible tube that needs to be pushed-through and propagate within the interior of a long duct, and specifically a duct having many bends and curves, and flexible, stretchable walls, and a diameter substantially larger than the inserted tube's diameter. The invention will be demonstrated herein on the application of endoscopy of the GI system, though it is applicable to other organic or inorganic systems as well.

As mentioned in the introduction, the nature of the intestine (e.g., dimensions, mechanical properties, etc) imposes tradeoffs on the endoscopy equipment and procedure. In order to minimize the forces exerted on the intestinal walls (and thereby minimize patient discomfort and chances to perforate the intestinal walls), it is preferred to use a very flexible endoscope. However, a very flexible endoscope would fail to traverse a long distance through the curved and bent intestine. This is mostly because the diameter of the intestine ***D*** is substantially larger than the diameter ***d*** and diameter of maximum curvature (namely the smallest curvature diameter) ***R*** of the very flexible endoscope, as schematically depicted in Fig.18(a). It is to be noted that an appropriate very flexible endoscope of diameter close to the intestinal diameter cannot be realized with common, known materials. If a very flexible tube needs to be inserted and pushed-through a long and curved duct, the duct's diameter should preferably be just a bit larger than the flexible tube's diameter (and preferably smaller than the smallest curvature diameter of the flexible tube), thereby allowing the duct's internal walls to support the tube while it progresses, force it to follow the duct's bends and curvature, and prevent the tube from bending and curving upon itself instead of progressing forward through the duct. This is substantially the case in catheterizing and angioplasty of the coronary system, as the diameter of the arteries is just a bit larger than the diameter of the flexible catheter guide, thus facilitating its pushing through. In contrast, a very flexible endoscope would tend to bend upon itself within the large-diameter intestine, rater than to progress forward, as schematically illustrated in Fig.18(b). As implied by Fig.18(b), further pushing the very flexible endoscope would cause it to further bend upon itself within the intestine and to form additional curves instead of progressing forward.

Accordingly, the present invention affords a method (and variations thereof) and apparatus or devices (and variations thereof) for overcoming the above mentioned tradeoff and maneuvering difficulty, as well as other propagation obstacles and difficulties. Generally, it uses two tubes, inserted one within the other, for propagating within a duct (e.g., of properties as described above). Each tube exhibits different properties relevant to the propagation within the duct, and they are propagated separately (each one in its turn) for short distances, alternately. In the case of GI push-endoscopy, one tube is more rigid (less flexible) and the other tube is very flexible. The external tube could be less flexible whereas the internal tube is very flexible, or vice-versa. For GI push-endoscopy, the conventional endoscope (e.g., colonoscope, gastroscope) can be the external, less flexible tube, whereas the internal very flexible tube can be an accessory, which is inserted within the instrument channel of the endoscope. The diameter of the internal tube is a bit smaller than the diameter of the instrument channel. This affords smooth and frictionless motion of the internal tube within the instrument channel in one hand, while allowing the instrument channel's walls to support the very flexible internal tube as it is pushed-through relative to the endoscope, and preventing it from bending upon itself instead of advancing within the instrument channel. In this configuration, the inner very flexible tube is first advanced in the intestine beyond the endoscope's head for a short distance, and then the endoscope follows it till their leading (namely front) ends are in-line. This sequence is repeated over and over as needed. In a preferred embodiment to be described in the next section, the inner very flexible tube comprises an anchoring means at its front end, such as an inflatable balloon, which is anchored (e.g., inflated) to the intestinal walls after advancing ahead of the endoscope (without damaging the

intestine), for allowing some tension in the inner tube and for preventing it from retracting backwards when the endoscope slides forward on the inner tube. In this configuration, the accessory acts as a guide that leads the endoscope forward through the portion of the intestine it has advanced relative to the endoscope. The endoscope, on the other hand, acts as a supporting (namely confining) channel that enables the inner very flexible tube to advance a long distance through the intestine, overcoming its limiting flexibility. The inner very flexible tube exhibits superior passage through curves and tight bends of the intestine, while the less flexible endoscope exhibits superior long-distance pushability. Differently stated, the inner flexible tube affords the short-term flexibility and bendability, while the less flexible endoscope affords the long-term propagation capability. Thus, this combined apparatus and propagation method afford both high maneuverability and tight bends passage, together with traversing a long distance, and without exerting high forces on the intestine. Instead of trying to afford all the appropriate characteristics of the endoscope in one tube as done in conventional endoscopes, an approach that results in characteristics tradeoffs, the approach of the present invention is to comprise the endoscope of two or more tubes of different characteristics, and let the superior characteristics of each tube to be expressed by alternate propagation of the tubes, thus avoiding or minimizing the tradeoff.

In the preferred embodiment with the anchoring means, after anchoring the flexible accessory to the intestine (by inflating its head balloon which in turn clamps the intestine), the accessory acts like a rail, which guides the surrounding endoscope through. It is thus optional that prior to sliding the endoscope on the anchored flexible accessory, the flexible accessory is pulled gently, thus stretching it a bit and reducing or eliminating any freedom and tendency of the endoscope not to follow its way. The anchored flexible tube, when it is stretched, can better resist the endoscope's counter-forces while guiding it forward.

It is appreciated that the present invention also overcomes additional progressing and maneuvering obstacles of traditional flexible endoscopy, such as the endoscope's head getting stuck in the sidewalls of the intestine (mostly the colon), unplanned curving of the endoscope while pushed-through, such as loops or "S shape" formation of the endoscope body, and others. Few examples related to conventional colonoscope during colonoscopy, which are reduced or eliminated by the apparatus of the invention, are illustrated in Fig.19. Fig.19(a) illustrates a difficulty of the colonoscope's head to propagate, and Fig.19(b) illustrates "S shape" formation of the colonoscope's body.

It is further appreciated that this approach is applicable to various other systems, in which the tradeoffs and limitations are of different nature. Another example is of a duct having a high friction coefficient of its inner walls, thus making it difficult for a tube (of close diameter) to pass through. In this example, the difficulty is bypassed by using the two tubes configuration with the anchoring means of the very flexible tube, as described here above. Thus, instead of trying to push the external tube through against the high friction of the interior duct's walls, the inner tube is first advanced a short distance without friction (as its diameter is much smaller that the duct's internal diameter), then its

anchoring means in anchored to the duct's internal walls, and then the external tube is pushed forward against the anchored internal tube. Having the guideness of the anchored inner tube, the external tube is able to slide around it and overcome its friction with the duct.

It is yet appreciated that the flexible accessory can be pulled out of the instrument channel if not needed, or if another accessory is required for treatment. The accessory could be used as a routine during the whole progressing process of the endoscope, or in contrast only in difficult to pass portions of the intestine.

It is appreciated that other features, variations and advantages of the present invention, as demonstrated by the described embodiments, would be apparent to one skilled in the art, though not explicitly noted herein, and should thus be considered in the scope of the invention. It is further appreciated that the scope of the invention is not limited to the apparatuses, devices and accessories of the invention, but also includes the various methods, procedures and sequences of using them.

THE INVENTION – DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

The present invention and the described embodiments are best understood with relation to the accompanying figures. It is appreciated that in some of the figures only the most relevant details are depicted, while some details and elements are omitted. It is also appreciated that in some of the figures, the correct ratio between elements in the figure is not necessarily maintained. It is further appreciated that when referring to embodiments of *the former application*, the same terminology is often used, but with a different numbering of elements in the figures.

An embodiment encompassing a first aspect of the present invention, as described above in the summary of the invention, is the MR of *the former application* with few balloon segments comprising each of the two (front and rear) clamping units. Fig.1(a) is a schematic front view of the MR and Fig.1(b) is a schematic rear view of the MR, which comprises four balloon segments in each clamping unit, in a scenario where both clamping units are fully inflated symmetrically and clamping the intestinal wall. Fig.1(a) shows the front clamping unit **20**, comprised of four balloon segments **22, 24, 26,** and **28.** Fig.1(b) shows the rear clamping unit **30**, comprised of four balloon segments **32, 34, 36,** and **38.**
The following figures, Fig.2 to Fig.9, schematically depict examples of different positioning and angles of the MR with respect to the intestinal walls and longitudinal axis, according to appropriate inflation/deflation of the various balloon segments of the front and rear clamping units. It is appreciated that various other positions and angles are achievable through other appropriate configurations of segments' inflation/deflation, as will be apparent to one skilled in the art. It is further appreciated that the cross-section of

the intestinal wall is schematically depicted circular for the sake of simplicity, while the actual intestinal cross-section could vary from circular shape, conforming to the balloon segments, in accordance with their degree of inflation. It is also appreciated that the exact cross-section contour of each balloon segment depends upon its degree of inflation as well as its relaxed shape, mechanical properties, fabrication conditions etc., and the invention as described herein is applicable with a variety of balloons shapes and properties. It is appreciated as well that the figures are aimed for illustration and demonstration, and are thus simplified illustrations of the system, demonstrating the invention concept and the additional degrees-of-freedom afforded by the invention.

Fig.2 is an example scenario in which the MR and intestine longitudinal axes are parallel, but the segments' inflation and clamping is asymmetric, as illustrated in Fig.2(a) and Fig.2(b) which are front and rear views of the MR within the intestine, respectively: the top segments **22** and **32** are almost fully deflated; the bottom segments **24** and **34** are fully inflated; the right segments **26** and **36** and the left segments **28** and **38** are partially (say around half) inflated. Fig.2(c) is the corresponding rough side view of the MR within the intestine, illustrating the resulting position of the MR relative to the intestinal walls: the MR is closer to the intestine's upper wall, and further from the bottom wall. The doted line and the broken line correspond to the longitudinal axes of the MR and the intestine, respectively. It is appreciated that the intestine could be curved or bent rather than straight (as shown in the figure for simplicity).
Fig.3 is an example scenario in which the MR and intestine longitudinal axes are parallel, but the segments' inflation and clamping is asymmetric, as illustrated in Fig.3(a) and Fig.3(b) which are front and rear views of the MR within the intestine, respectively: the top segments **22** and **32** are fully inflated; the bottom segments **24** and **34** are almost fully deflated; the right segments **26** and **36** and the left segments **28** and **38** are partially (say around half) inflated. Fig.3(c) is the corresponding rough side view of the MR within the intestine, illustrating the resulting position of the MR relative to the intestinal walls: the MR is closer to the intestine's bottom wall, and farther from the upper wall. It is appreciated that the vicinity of the MR to a desired wall of the intestine could be continuously varied by appropriate inflation of the balloons segments. It is further appreciated that the MR could be also positioned closer to the right or left wall of the intestine, as illustrated in Fig.4 and Fig.5 respectively. It is also appreciated that not only horizontal or vertical displacement of the MR from concentric position is available, but also any combination thereof. For example, Fig.6 illustrates a scenario in which the MR is closer to the right intestinal wall, but is also positioned upwards. The crossing-point of the doted lines in Fig.6 denotes the center of the intestine's cross-section (namely its longitudinal axis). In Fig.4, Fig.5 and Fig.6, drawings (a) correspond to the MR front view, and drawings (b) correspond to the MR rear view.

Fig.7 is an example scenario in which the longitudinal axes of the MR and intestine are not parallel, but rather exhibit a substantial angle between them. As shown in Fig.7(c), which is a rough side view of the MR within the intestine, the MR head is pointing upwards while its tail is pointing downwards. As illustrated in Fig.7(a) and Fig.7(b) which are front and rear views of the MR within the intestine, respectively, this positioning is achieved by the following configuration of balloons segments'

inflation/deflation: the top segment of the front clamping unit **22** and the bottom segment of the rear clamping unit **34** are almost fully deflated; the bottom segment of the front clamping unit **24** and the top segment of the rear clamping unit **32** are fully inflated; the right segments **26** and **36** and the left segments **28** and **38** are partially (say around half) inflated.

Fig.**8** is another example scenario in which the longitudinal axes of the MR and intestine are not parallel, but rather exhibit a substantial angle between them. As shown in Fig.8(c), which is a rough side view of the MR within the intestine, the MR head is pointing downwards while its tail is pointing upwards. As illustrated in Fig.8(a) and Fig.8(b) which are front and rear views of the MR within the intestine, respectively, this positioning is achieved by the following configuration of balloons segments' inflation/deflation: the top segment of the front clamping unit **22** and the bottom segment of the rear clamping unit **34** are fully inflated; the bottom segment of the front clamping unit **24** and the top segment of the rear clamping unit **32** are almost fully deflated; the right segments **26** and **36** and the left segments **28** and **38** are partially (say around half) inflated. It is appreciated that the balloons segments substantially grab the intestinal walls, which conform to their shape, in contrast to the simplified illustrations of Fig.7(c) and Fig.8(c).

Similarly, the MR can point to the right, by combining for example the front balloon segments configuration of Fig.4(a) and the rear balloon segments configuration of Fig.5(b). Likewise, the MR can point to the left, by combining for example the front balloon segments configuration of Fig.4(b) and the rear balloon segments configuration of Fig.5(a).

It is appreciated that any superposition of such up-down and right-left positioning angles of the MR relative to the intestine are affordable, by appropriate inflation/deflation of the balloons segments, similarly to the scenario of Fig.6. It is appreciated that such angles can be wider or narrower as needed. For example, by originating in the configuration of Fig.7, inflating a bit segments **22** and **34** and deflating a bit segments **24** and **32**, a more moderate, less wide angle is realized, as illustrated in Fig.9.

It is thus appreciated that the present invention MR allows a continuous and broad range of positioning and access angles of the MR and pushed-through accessory relative to the intestinal walls. This attribute can help in navigation and finding the way through the intestine, mostly in regions that are not inflated (namely not insufflated) or that are tightly bent. Another major benefit of this MR, is that it facilitates a more controlled, accurate and broad range of access orientation, positioning and distance of the MR head and accessories to an inspected or treated point in the intestine. Fig.10 roughly illustrates an example of a polyp **40** to be removed by an accessory, which is located in a bent region of the intestine, and is thus difficult to access. Fig.10(a) illustrates an example access angle of the present invention MR, while Fig.10(b) and Fig.10(c) illustrate example access angles of typical inchworm MR **50** and conventional push-colonoscope **60**, respectively. The broken line in each of these illustrations denotes the access line of a push-through accessory for taking biopsy of the polyp or removing it. As seen in the illustrations, only the present invention MR affords access to the polyp **40**. It is appreciated that many other scenarios exist, in which the invention MR exhibits superior access to points in the intestine, as apparent to one skilled in the art.

Many segmentation alternatives of the front and rear clamping-units are applicable, as would be apparent to one skilled in the art, whereas each specific segmentation configuration may possess its own advantages and disadvantages, in terms of system and control simplicity, maneuvering and angles range, similarity to conventional push-endoscopy, and so.
For example, the clamping units could be divided to a different number of segments (other than four). Fig.11 depicts an example in which each clamping unit is divided to three segments, having the same orientation, as illustrated in the MR front view of Fig.11(a) and rear view of Fig.11(b). Fig.12 depicts an example in which each clamping unit is divided to three segments, having different orientation, as illustrated in the MR front view of Fig.12(a) and rear view of Fig.12(b). Fig.13 depicts an example in which each clamping unit comprises two segments, having different orientation. The segments of the front clamping-unit are disposed horizontally as illustrated in Fig.13(a), and account for horizontal (right-left) motion of the MR head. The segments of the rear clamping-unit are disposed vertically as illustrated in Fig.13(b), and account for vertical (up-down) motion of the MR tail.

In a yet alternative segmentation example, one clamping unit (e.g., the front clamping unit) could be segmented, while the other clamping unit (e.g., the rear clamping unit) is not segmented but rather composed of a single, ring-shaped balloon. A specific example of this configuration would be a four-segment front clamping unit, as depicted in Fig.1(a), together with a rear clamping unit as described in *the former application*. Such a configuration would exhibit an easier control and mechanics, but may afford a more limited angle-range than the embodiment of Fig.1(a) and Fig.1(b). Yet alternatively, each clamping unit could be divided to a different number of segments, and/or to segments of different size within each clamping unit.

It is appreciated that the MR can propagate (advance or retract) within the intestine as described in *the former application*, while possessing an angle and/or non-concentricity with respect to the intestine's longitudinal axis. This allows for inspecting the sides of the intestine while passing through, resemble to a higher extent the conventional push-endoscopy procedure, and further assist the MR in passing through tight bends of the intestine, by utilizing appropriate angles and non-concentricity. Differently stated, the attributes of the invention may apply both to static (namely when the MR is not propagating) and dynamic (namely during MR motion) scenarios.

It is appreciated that angles much wider than the angle of Fig.7(c) are achievable with the invention MR, since the intestine stretches around the MR and the balloons and conforms to its shape (in contrast to the simplified illustrations in the figures, which depict straight and stiff intestinal walls). It is thus applicable, if needed, to invert the direction of the invention MR, such that its head points backwards to the rear bundle (namely so that advancing would mean progressing towards the intestinal opening, e.g., the anus). This action is sometimes performed during conventional push-endoscopy, by fully bending the endoscope's head and then pushing it forward, and is often referred to as performing a "U shape". A "U shape" is beneficial for inspecting points that are not visible during regular inspection, and mostly for inspecting the most distal part of the intestine (e.g., the

rectum). Fig.14 roughly illustrates an example sequence of inverting the invention MR, through steps (a) to (h), as depicted in Fig.14(a) to Fig.14(h), respectively. Insufflation or suction of the intestine could be performed as needed during the inversion process for optimization of the MR wrapping by the intestine, through the rear bundle hollow tube, as described in *the former application*.

As mentioned here above, the amount of inflation/deflation of the balloons segments is controlled by appropriate pneumatic valve (or valves) in the MR tail, according to the description in *the former application*. The MR pneumatics is fed either through the rear bundle hollow tube or through dedicated pneumatic tube (or tubes) within the rear bundle. The amount of inflation could be controlled electrically, by controlling the opening duration and/or amplitude of the valve, or pneumatically, by modifying the pressure in the pneumatic line, or by combination thereof. The various needed supplies (e.g., electrical power, air pressure, rinsing fluid, vacuum, illumination source, etc) are generated by an endoscopy central supply and processing unit. This unit also receives the incoming signals from the MR (e.g., video signal, CCD output, optical image, etc), processes them as needed and displays them on a monitor. This unit also carries further functions as needed, such as collecting and saving data and images, performing algorithms on relevant data, filtering, etc. This unit may be a dedicated unit for the endoscope MR, but may alternatively be a conventional push-endoscopy supply and processing unit. For example, For the purpose of GI endoscopy, a conventional unit of Olympus Optics Co (Japan), Pentax Inc (USA), and so, could be used, by introducing an appropriate plug, which fits into the conventional unit's socket, and transfers all the relevant I/O between the conventional unit and MR. Fig.15 schematically depicts an example MR gastrointestinal endoscopy system and connections. The supply and processing unit **110** is a conventional push-endoscopy unit. In the example of Fig.15, it is a supply and processing unit by Olympus Optics Co, Japan. This unit **110** encompasses all needed equipment and components for electrical, optical, pneumatic (insufflation/suction etc) and fluid supplies, data reception and processing, storage and displaying, such as the CV-160 Video System, the OFP Flushing Pump, a monitor for displaying video images, power supply, etc (alternatively, it can be a dedicated supply and processing unit, especially designed for the endoscopy MR, encompassing the above mentioned functionalities, as well known in the art). A MR controller **120** is connected to the unit **110** through an adapter plug **122**, which is compatible with the socket **112** of the unit **110** (in the case of a dedicated supply and processing unit, the MR controller is an integral part of this unit, eliminating the need of an adapter plug). The MR controller **120** controls and operates the MR according to command signals received through the user control **130**. The MR controller also receives the appropriate supplies from the supply and processing unit **110** (electrical power, illumination, air pressure/vacuum, flushing water, etc), tunes them if necessary (e.g., reduces electrical voltage, sets appropriate air pressure for pneumatic usage), and distributes and passes them on to the MR, as required by its operation and by the user's commands. The MR controller **120** also passes the signals and outputs received from the MR to the supply and processing unit **110**, for processing, displaying, storage and so. The MR controller **120** encompasses all the electronics, control hardware and software, pneumatics and vacuum regulation, tuning and control means, etc., as needed for its operation. The MR controller **120** is connected

via a flexible bundle **140** to the user control **130**. The flexible bundle **140** encompasses all the needed wiring, tubes, fiber optics and so, for distributing the various supplies and operation commands to the MR **160**, for carrying to the MR controller **120** the inspection signals transmitted by the MR **160**, and for communication between the MR controller **120** and the user control **130**. The user control **130** receives the user's (e.g., physician, gastroenterologist) commands via a control interface comprising buttons, actuators, knobs and so as needed, and transmits them to the MR controller **120**. For example, the control interface may comprise a joystick, through which the user can control continuously the direction and amplitude of the positioning angle of the MR **160** with respect to the intestinal longitudinal axis. The joystick's state is transformed to corresponding electric signal, which is transmitted from the user control **130** to the MR controller **120** via the flexible bundle **140**. The MR translates the positioning electric signal to appropriate inflation/deflation of the various balloons segments of the MR **160**, as described in details here above, and sends the appropriate signals (e.g., pneumatic valves' positions) and supplies (e.g., pneumatic lines' appropriate air pressure/vacuum) to the MR, through the flexible bundle **140** and the following rear bundle **150**. The user control **130** may further comprise a handle for controlling the direction and velocity of the MR propagation within the intestine, buttons for applying air pressure/vacuum for insufflation/suction, a button for applying flushing water, etc. The user control **130** further comprises a tubular orifice **132** through which endotherapy or other accessories are inserted to in-front of the MR head as needed, via the hollow tube of the rear bundle **150**. The rear bundle **150** is described in details in *the former application*. It is appreciated that even though the user control **130** is positioned between the rear bundle **150** and the flexible bundle **140**, all the appropriate wiring, tubes, fiber optics and so are continuous between the MR controller **120** and the MR **160**. Thus, for example, the air pressure/vacuum for insufflation/suction is flowing directly between the MR controller **120** and the MR **160**, and so on.
Fig.16 schematically depicts an example MR endoscopy system in which some of the supplies are supplied by the conventional push-endoscopy supply and processing unit **110**, while other supplies are supplied by a separate, dedicated supply unit **170**. This might be desired, for example, if the conventional unit **110** cannot afford the needed air pressure and capacity, the needed electrical voltage, current or power, and so.

It is appreciated that other mechanisms and methods for clamping units are applicable with the present invention MR, rather than the inflated/deflated balloons. Alternative clamping mechanisms, such as described in *the former application* or else, are also included within the scope of the present invention MR, as long as they could be segmented to few clamping segments within each clamping unit. It is also appreciated that variations of the invention MR, as described in *the former application* or as will be apparent to one skilled in the art and maintain the spirit of the invention, should be included within the scope of the invention.

It is appreciated that the invention is applicable to many other uses, fields and applications, which should thus be considered within the scope of the invention. For example, a variation of the present invention MR could be beneficially used for oil or gas searching. Hence, a bigger, massive and strong variation of the invention MR, referred to

hereinafter as "drilling robot", includes a rock drilling head instead of the endoscopy MR head, and an appropriate, long rear bundle (which could be comprised of many segments sequentially). While the drilling head drills downwards through the rock, the angle of the drilling robot can be changed as needed by appropriate inflation/deflation of the balloons segments, as described in details here above. This results in a curved drilling path, rather than the straight, vertical drilling path performed by conventional rock-drilling methods and equipment. Thus, with the aid of mapping the rock layers prior to drilling, as well known in the art, the drilling path could be designed to bypass and avoid hard rock layers and regions, and mostly propagate through soft rock layers and regions, as roughly illustrated in Fig.17 (which is not to scale), which is a cross-section of the oil/gas searching region. This saves drilling time and driller heads.

As described here above in the former sections, another object of the invention is to provide methods, devices and accessories for improved maneuverability and pushability during flexible push-endoscopy and the like. In general, it relies upon two (or more) flexible tubes, one inserted within the other, having different properties (e.g., mechanical properties such as flexibility, bending-strength, friction with the duct's interior, etc), which are propagating in conjugation, alternately. The different properties of each tube are chosen as needed by the application and procedure, and the alternate propagation of the tubes allows each tube to exhibit its superior properties, thus avoiding a tradeoff which would have been the consequence of using a single tube. Fig.20 schematically depicts the apparatus **200** of two long tubes, an internal (namely inner) tube **210** inserted within an external tube **220**, the apparatus being inserted within a long duct **230**, through which it propagates. The external tube **220** comprises a channel **222**, through which the internal tube is inserted, as depicted in Fig.20. Fig.20(a) is a front view cross-section and Fig.20(b) is a side view cross-section of a portion of the long apparatus **200** within the long duct **230**. The internal tube **210** and external tube **220** can smoothly slide back and forth one within the other. Preferably, there is a gap (namely spacing) **240** between the two tubes. The gap **240** is wide enough to facilitate smooth, easy and frictionless motion of the tubes relative to each other, and not too wide, thus preventing the inner tube **210** from bending and curving upon itself within the external tube **220**, but rather forces and confines the inner tube **210** to advance or retract within the external tube **220**, as it is pushed or pulled relative to it, respectively. As implied herein, the diameter of the external tube's channel **222** is preferably smaller than the smallest curvature diameter of the inner tube **210**. The propagation of the apparatus **200** in the duct **230** is performed by alternately pushing each of the tubes a short distance, while holding still or even pulling the other tube. A short distance herein refers to a distance that is typically longer than the diameter of the duct **230** but is substantially shorter than the length of the duct **230** (and by nature, than the length of the apparatus). In general, the length of the short distance propagation depends upon the application and the properties of the duct and the tubes. In GI endoscopy, for example, the short distance may be of the order of the distance between adjacent bends of the intestine, or even shorter.

Fig.21 illustrates an example of propagation sequence of the apparatus **200** in the duct **230**, in which the inner tube **210** is first advanced relative to the external tube **220**, and then the external tube **220** is advanced while the inner tube **210** is held stationary (with

respect to the duct **230**). The propagation sequence comprises the following steps (a) to (c), as illustrated in Fig.21(a) to Fig.21(c), respectively, which roughly depict the front (namely leading) end of the apparatus **200**:

(a) Starting position – the front (namely leading) ends of both tubes are approximately aligned.
(b) The inner tube **210** is advanced a short distance relative to the external tube **220** and the duct **230** by pushing its rear end (which is out of the duct, beyond its rear opening), while the external tube **220** is held stationary relative to the duct **230**.
(c) The external tube **220** is advanced a short distance relative to the inner tube **210** and the duct **230** by pushing its rear end (which is out of the duct, beyond its rear opening), while the inner tube **210** is held stationary relative to the duct **230**. The external tube **220** is thus sliding around the inner tube **210** and is guided by it. This advancing step is completed when the inner tube **210** and the external tube **220** are approximately aligned again, as in step (a), thus returning to the starting position, but yet a step forward (as denoted by the arrow in the figure).

The steps of the This sequence comprise an advancing step of the apparatus **200**, which is repeated over and over again as needed, resulting in a long, multi-step distance propagation of the apparatus **200** in the duct **230**.

Fig.22 illustrates an example of propagation sequence of the apparatus **200** in the duct **230**, in which the external tube **220** is first advanced relative to the inner tube **210**, and then the inner tube **210** is advanced while the external tube **220** is held stationary (with respect to the duct **230**). The propagation sequence comprises the following steps (a) to (c), as illustrated in Fig.22(a) to Fig.22(c), respectively, which roughly depict the front (namely leading) end of the apparatus **200**:

(a) Starting position – the front (namely leading) ends of both tubes are approximately aligned.
(b) The external tube **220** is advanced a short distance relative to the inner tube **210** and the duct **230** by pushing its rear end (which is out of the duct, beyond its rear opening), while inner tube **210** is held stationary relative to the duct **230**.
(c) The inner tube **210** is advanced a short distance relative to the external tube **220** and the duct **230** by pushing its rear end (which is out of the duct, beyond its rear opening), while the external tube **220** is held stationary relative to the duct **230**. The inner tube **210** is thus sliding within the external tube **220** and is guided by it. This advancing step is completed when the inner tube **210** and the external tube **220** are approximately aligned again, as in step (a), thus returning to the starting position, but yet a step forward (as denoted by the arrow in the figure).

The steps of the This sequence comprise an advancing step of the apparatus **200**, which is repeated over and over again as needed, resulting in a long, multi-step distance propagation of the apparatus **200** in the duct **230**.

It is appreciated that any combination of the sequences depicted in Fig.21 and Fig.22, or other sequences, are also applicable as needed. It is also appreciated that the steps are not necessarily of the same length.

In the application of flexible endoscopy, such as GI endoscopy, the different properties of the two tubes **210** and **220** can preferably be the degree of flexibility as suggested here above, with either the inner tube **210** or the external tube **220** being very flexible and

highly bendable, while the other tube being less flexible, more rigid. In a specific embodiment, the inner tube **210** is very flexible and bendable, and the external tube **220** is less flexible and more bending-resistant. In yet a specific embodiment, the less-bendable external tube **220** is a conventional flexible GI endoscope, such as a colonoscope or gastroscope, as commonly used in GI endoscopy, such as the model CF-Q160AL Video Colonoscope, a product of Olympus Optics Co (Japan), or the like. In this specific embodiment, the instrument channel of the GI endoscope is utilized also as the external tube's channel **222**, through which the internal tube **210** is inserted. Yet in this specific embodiment, the inner tube **210** is a long and very flexible accessory tube, with diameter smaller than the diameter of the channel **222**. In the above-mentioned example of the model CF-Q160AL Video Colonoscope, which comprises a 3.7 millimeter diameter instrument channel, the inner tube's diameter may be of 1.5 to 2.5 millimeter diameter. This ensures a sufficient gap **240** for smooth insertion and relative motion of the inner tube **210** within the instrument channel **222** (as well known and commonly applicable with a variety of GI endotherapy accessories), as well as allowing suction, rinsing or insufflation of the intestine through the instrument channel while the inner tube **210** is inserted and used for propagation. Yet, the gap **240** is small enough to allow the instrument channel to confine the inner tube **210**, support and force it to advance or retract within the channel **222** as it is pushed or pulled respectively, at its rear end (out of the endoscope's instrument channel).

Preferably, The inner tube **210** comprises an anchoring means **250** for anchoring it to the internal walls of the intestine, without causing any damage to the intestine. Thus, the inner tube **210** is anchored to the intestine (or generally to the duct **230**) by the anchoring means **250** after it has propagated the short length within the intestine and before the endoscope (or generally the external tube **220**) is pushed forward. This prevents the inner tube from retracting back while the endoscope is pushed forward, and forces the endoscope to follow the route of the leading inner tube **210**. After the endoscope has propagated to approximately align with the front end of the inner tube **210**, the anchoring means is released from the intestinal walls, thereby allowing the inner tube **210** to advance another short distance for the next propagation step. In its released state, the anchoring means **250** should be of small size and have minimal friction with the intestinal walls, thus not disturbing the propagation of the inner tube **210**. It is also noted that when the inner tube **210** is inserted within the instrument channel **222**, the diameter of the anchoring means **250** should be smaller than the diameter of the instrument channel **222**.

Yet preferably, the front end of the inner tube **210** is smooth and not sharp, and has a shape that prevents damage to the intestine while it is used (e.g., perforation of the intestinal wall).

Fig.23 roughly depicts an embodiment accessory inner tube **210**, in which the anchoring means **250** is an inflatable balloon, which could be anchored to the intestinal walls by substantially inflating it through a hollow channel **252** within the inner tube **210**, until it clamps and grabs the internal walls of the intestine. The balloon is deflated as needed to allow the inner tube **210** to propagate within the intes
tine or to be inserted in the instrument channel **222**. Fig.23(a) is an illustration of a side-view cross-section of the apparatus front, as it is inserted through the instrument channel **222**. In this state, the inflatable balloon (namely the anchoring means) **250** is fully

deflated, allowing it to pass through the narrow channel **222**. Fig.23(b) is an illustration of a side-view cross-section of the apparatus front portion, as it propagates through the duct 230, ahead of the external tube (namely the endoscope) **220**. In this state, the balloon **250** is almost fully deflated, but yet inflated to a small amount, thus constructing a rounded and smooth shape of the inner tube's front end, and preventing any damage to the intestinal walls. Fig.23(c) is an illustration of a side-view cross-section of the apparatus front, when it is anchored to the intestinal walls. In this state, the balloon **250** is fully inflated, thereby grabbing and clamping the internal walls of the intestine, and preventing any substantial relative motion between the inner tube **210** and the intestine (namely the duct) **230**. The balloon **250** resembles the balloons of the MR clamping units of *the former application*, in the sense that it clamps a wide enough area of the intestine, and allows sufficiently strong clamping without applying high local forces on the intestinal walls, and thus without causing any damage to the intestinal walls.

Fig.24 schematically depicts the progressing sequence of the apparatus of Fig.23, comprising a single propagation step. Progressing steps (a) to (e) of the sequence are roughly illustrated in Fig.24(a) to Fig.24(e), respectively:

(a) Starting position – the front (namely leading) ends of both tubes are approximately aligned. The inflatable balloon **250** is inflated to a small amount, enabling the advancing of the inner tube **210**, while forming a rounded front end of the inner tube **210** for preventing any damage to the intestine.

(b) The inner tube **210** is advanced a short distance relative to the external tube **220** and the duct **230** by pushing its rear end (which is out of the duct, beyond its rear opening), while the external tube **220** is held stationary relative to the duct **230**.

(c) The inflatable balloon **250** is fully inflated through the hollow channel **252** within the inner tube **210**, thereby clamping the duct **230** and anchoring the inner tube **210** to the duct **230**.

(d) The external tube **220** is advanced a short distance relative to the inner tube **210** and the duct **230** by pushing its rear end (which is out of the duct, beyond its rear opening), while the inner tube **210** is held stationary relative to the duct **230**. The external tube **220** is thus sliding around the inner tube **210** and is guided by it. This advancing step is completed when the inner tube **210** and the external tube **220** are approximately aligned again, as in step (a), but yet a step forward (as denoted by the arrow in the figure).

(e) The inflatable balloon is almost fully deflated, but a little amount of inflation is kept, to afford the rounded shape of the inner tube's front end (thereby preventing damage to the intestine). This step results in returning to the starting position, though a step forward.

As described in the summary of the invention, in a preferred method for using the two tubes apparatus, the flexible inner tube is pulled gently after anchoring it and prior to advancing the external, less-flexible tube. This stretching action of the inner tube affords superior guiding of the external tube by the leading inner tube, and further reduces or eliminates undesired bending or curving of the external tube, such as depicted in Fig.18(b). The following steps (a) to (f) give the propagation sequence with the pulling action of the inner tube:

(a) Starting position – the front (namely leading) ends of both tubes are approximately aligned. The inflatable balloon **250** is inflated to a small amount,

enabling the advancing of the inner tube **210**, while forming a rounded front end of the inner tube **210** for preventing any damage to the intestine.

(b) The inner tube **210** is advanced a short distance relative to the external tube **220** and the duct **230** by pushing its rear end (which is out of the duct, beyond its rear opening), while the external tube **220** is held stationary relative to the duct **230**.

(c) The inflatable balloon **250** is fully inflated through the hollow channel **252** within the inner tube **210**, thereby clamping the duct **230** and anchoring the inner tube **210** to the duct **230**.

(d) The inner tube **210** is pulled gently from its rear end (which is out of the body), to gently stretch the inner tube **210** against the anchored inflatable balloon **250**.

(e) The external tube **220** is advanced a short distance relative to the inner tube **210** and the duct **230** by pushing its rear end (which is out of the duct, beyond its rear opening), while the inner tube **210** is held stationary relative to the duct **230**. The external tube **220** is thus sliding around the inner tube **210** and is guided by it. This advancing step is completed when the inner tube **210** and the external tube **220** are approximately aligned again, as in step (a), but yet a step forward (as denoted by the arrow in the figure).

(f) The inflatable balloon is almost fully deflated, but a little amount of inflation is kept, to afford the rounded shape of the inner tube's front end (thereby preventing damage to the intestine). This step results in returning to the starting position, though a step forward.

Fig.25 is a rough side-view of the two tubes apparatus within the intestine, which depicts an example of applying these steps (a) through (f) for passing through a bent portion of the intestine. Fig.25(a) to Fig.25(e) correspond to steps (a) to (e), respectively. Step (f) was not depicted, as it is straightforward.

It is appreciated that the inner tube could be pulled and released as needed during the action of advancing the external tube, according to the real-time video image of the intestine (and the front portion of the inner tube 210, ahead of the external tube encompassing the visualization means), which is displayed on the monitor.

The inflatable balloon **250** can be inflated or deflated by any conventional means, as well known in the art. For example, a manual inflating/deflating device could be used, such as commonly used in blood pressure measurements. Such a device typically comprises a manual rubber balloon-pump, which inflates the balloon **250** by squeezing it, through a unidirectional pneumatic valve, which prevents the air in the inflated balloon **250** from escaping back to the balloon-pump. The device further includes a tunable valve for releasing the air pressure in the balloon **250** (namely deflating it). The device may further comprise a safety valve that releases over-pressure in the balloon **250** (whose value can be tunable and preset, as well known in the art), for preventing too high forces and damage to the intestinal walls. Alternatively, the inflation/deflation could be controlled and tuned electrically, utilize a pneumatic pressure/vacuum supply, and the like, as well known in the art. Yet alternatively, the inflation/deflation could be hydraulic rather than pneumatic, applying liquid high or low pressure to the balloon **250**, for inflation or deflation, respectively. It is further appreciated that the balloon **250** may encompass its own safety mechanism, for example by inflating in the longitudinal direction and not in the radial direction, when over-pressure is applied.

In a yet specific embodiment of the accessory inner tube **210** (with or without the anchoring means **250**), it further comprises maneuvering, steering and navigation capabilities, for controlling its propagation direction and for maneuvering it as it advances to a desired point or cavity within the intestine (or in general, within the duct **230**). Fig.26 illustrates an accessory inner tube **210**, which affords three steering degrees-of-freedom, which are independently controlled manually by manipulating the accessory inner tube's rear part out of the instrument channel **222**, as also depicted in Fig.26. Fig.26(a) illustrates the body of the accessory inner tube **210** within the instrument channel **222** of the external tube **220** (namely the endoscope in the example of Fig.26) and its front end ahead of them. Fig.26(b) depicts the rear part of the accessory **210**, which comprises a main-handle **212** for holding and manipulating it, and a pulling-handle **214** for pulling or releasing a wire within the accessory **210**, which in turn bends or straightens the accessory's head, as will be described at the following. The rear part of the accessory **210** further comprises an inflating/deflating device, as described here above, which is not depicted in Fig.26(b) for the sake of simplicity, and is attached to the accessory as commonly known in the art. The three manipulation axes A, B and C correspond to the following maneuvers:

<u>Axis A</u>: advancing or retracting of the accessory **210**, facilitated by pushing or pulling, respectively, the main-handle **212** or the part of the accessory **210** that is out of the instrument channel **222** but very close to it, as convenient, as depicted in Fig.26.

<u>Axis B</u>: rotating the accessory **210** clockwise or counter-clockwise, facilitated by turning clockwise or counter-clockwise, respectively, the main-handle **212** or the part of the accessory **210** that is out of the instrument channel **222** but very close to it, as convenient, as depicted in Fig.26. It is appreciated that the accessory inner tube **210** possesses a substantial torque-resistance (namely torsion-resistance), thereby allowing the rotation action of the accessory's rear part out of the instrument channel to rotate (preferably to the same amount or to a close amount) the accessory's head within the intestine. Nevertheless, the accessory **210** still exhibits the high flexibility, as discussed here above. Such long and narrow accessory tubes, which are very flexible and yet very torsion resistant, are well known in the art, and are commonly used in flexible endoscopy, catheterizing and angioplasty of the coronary system, and the like. A common type of endotherapy accessories is made of a winded metal spring tube, which affords both high bendability and torsion resistance, though other materials and constructions are widespread as well.

<u>Axis C</u>: Bending or straightening the head of accessory **210**, facilitated by pulling or releasing the pulling-handle **214**, respectively, as depicted in Fig.26 and as further elaborated here bellow.

Fig.27 depicts an example of facilitating the bending or straightening of the accessory's head through pulling or releasing the pulling-handle **214**, respectively. The example accessory inner tube **210** comprises an inner tube **211**, which is placed within a surrounding tube **216** of a bit larger diameter (though small enough to allow all properties of the inner tube accessory **210** as described in the invention), and is attached to its upper internal wall, as depicted in Fig.27. The wire **217** is attached and fixed to the inner tube **211** a small distance ahead of the surrounding tube **216** (typically 1 centimeter or so), and is passing through the surrounding tube **216** all the way to the pulling-handle **214**, to

which it is attached. A mechanical spacer **218** separates the wire **217** and the inner tube **211** at the front end of the surrounding tube **216**, facilitating a small angle between the inner tube **211** and the front end of the wire **217** in the released position (in which the inner tube **211** is straight). When the pulling-handle **214** is pulled, the wire pulls backwards the inner tube **211**, thereby bending it as illustrated in Fig.26(a). The amount of bending of the inner tube's head is continuously dictated and controlled by the amount of pulling of the pulling-handle **214**.
The separate control and manipulation of the three axes A, B, and C as described above, enables the accessory **210** to be targeted and steered toward a desired point of the intestine, and to find its way forward through the intestinal cavity. It is appreciated that various other embodiments and configurations exist for manipulating and steering an accessory **210** within the intestine, as implied by the description here above, and as will be apparent to one skilled in the art. Such embodiments and configurations are thus to be included within the scope of the invention.

In a yet specific embodiment, the accessory inner tube **210** further comprises a visualization means at its front end (e.g., a fiber optic, a CCD, a micro-camera, etc), instead of or in addition to the external tube (e.g., the flexible endoscope, an endoscope MR), and means for displaying the optical images gathered by it.

It is appreciated that the usage of a flexible-endoscope's instrument channel and a dedicated endoscopic accessory for assisting propagation and maneuvering are novel by themselves, and are thus claimed herein for protection within the present provisional patent application.

It is appreciated that the invention two tubes apparatus can be utilized also for MR endoscopy, not just in push-endoscopy. For example, it may be desired to insert the MR from the upper GI tract: from the mouth, through the esophagus and the stomach, to the duodenum, in order to examine the upper small intestine, or the like. However, some MR configurations may exhibit a difficulty to traverse the stomach, which is substantially wider than the esophagus and the small intestine, by their own locomotion. Additionally, as the rear bundle of the MR is very flexible and highly bendable, it cannot be utilized to push the MR through the stomach by pushing its tail out of the body. In such cases, a less flexible, more rigid inner tube can be inserted within the hollow tube of the rear bundle of the MR, to afford the semi-rigidity about that of a conventional push-gastroscope. This combined apparatus is pushed through the mouth, esophagus and stomach, with the inner tube's front end aligned with the MR head, till the MR reaches the duodenum. Then, the less flexible inner tube is pulled out of the MR and rear bundle's tube, and the MR propagates further within the small intestine by its own locomotion. An inner tube with anchoring means can be used, in order to clamp the inner tube to the concentric hollow tube of the MR, thereby forcing the MR to progress along with the inner tube.
Another example, applicable both for conventional push-colonoscope and for endoscope MR, is the passage from the ascending colon to the ileum (the end of the small intestine) through the Cecum. An inner tube accessory as described above, and moreover such an inner tube accessory with steering and maneuvering means as described above, is most beneficial for passing from the large intestine to the small intestine through the cecum, a

procedure that is very difficult to perform with a conventional colonoscope. When the colonoscope or the endoscope MR is close to the cecum, the very flexible inner tube with the steering and maneuvering capability is advanced and pointed to pass through the ileo-cecal valve and to the small intestine. After it has passed through and the anchoring means is clamped to the small intestine's walls, the colonoscope or the endoscope MR is advanced while guided by the inner tube to pass through the ileo-cecal valve to the small intestine.

SAMPLING ACCESSORIES

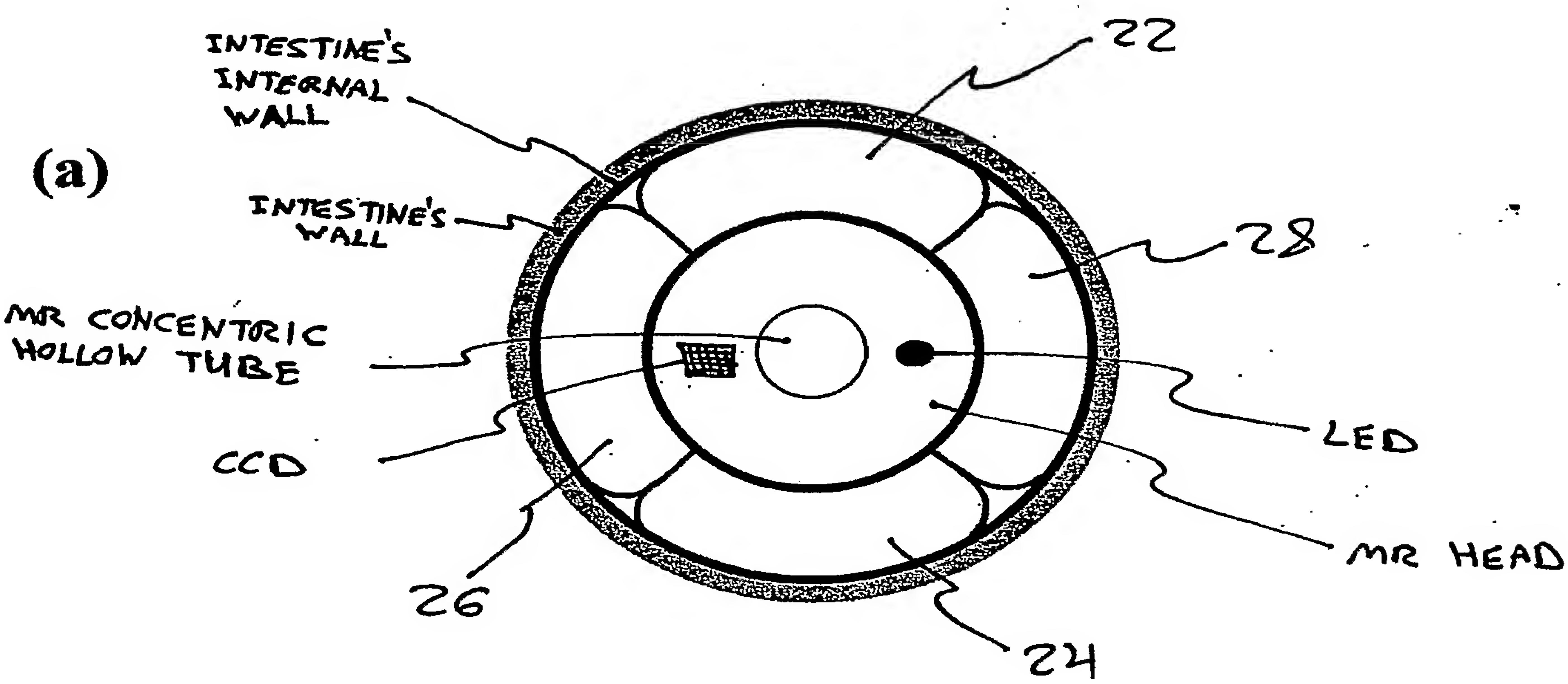
The former application describes in details a sampling accessory for taking samples of cells, fluids and the like from the interior of the colon, or another organ as needed. This sampling may be facilitated through a flexible long and narrow accessory, which is inserted into the organ (e.g., the colon) through its opening (e.g., the anus), and takes relevant sampling or biopsy of the organ's interior. Such a sampling exam could be related to endoscopy (e.g., for surveillance after an endoscopy with findings, for gathering data prior to an endoscopy, etc), but may also be performed as needed with no relation to an endoscopy.

The present invention considers a specific application of such a method and accessory, which is gynecological sampling of the feminine organs, e.g., the vagina and/or the cervix. Taking a vaginal swab or a cervical swab is a common gynecological procedure, which is commonly done by a specialized gynecologist. For example Pap smear, which is a cervical cancer screening test that is looking for abnormal cells or changes on the cervix, is part of the gynecological annual exam. Conventionally, it is performed by inserting a speculum (an instrument which allows visualization of the cervix) into the vagina, which opens the way for a sampling stick that is inserted by the gynecologist for obtaining cells for the Pap smear by swabbing the cervix. The specimen is then sent to a laboratory to be examined for signs of cancer and other abnormalities. The sampling accessory of *the former application* can be utilized to perform a Pap smear or any other vaginal or cervical sampling and swabbing as needed. To this end, the sampling accessory is of the appropriate length to allow taking sample from the desired depth of the organ when it is fully inserted. Furthermore, the sampling arms of the sampling accessory comprise an appropriate absorbent layer at their tip (preferably of the same material used in the conventional sampling stick), for collecting the relevant specimen (e.g., cervical cells for Pap smear, bacteria cells, etc). After the sampling arms are extracted and pressing the interior of the sampled organ, the sampling accessory can be rotated and/or pulled-and-pushed alternately with small amplitude, to allow sufficient swabbing of the organ. If desired, the sampling arms can be inserted back into the external tube of the sampling accessory, to protect the specimen while the sampling accessory is pulled out of the organ. It is appreciated that the above-described sampling could be performed by a gynecologist, or be suitable for self-use by the patient. It is further appreciated that the specimen could be sent to the laboratory for examination, while for some screening tests it could be applicable to provide the sampling accessory

along with a self-screening test kit, for performing both the sampling and the examination by the patient at home, similar in a sense to self-usage pregnancy test kits.

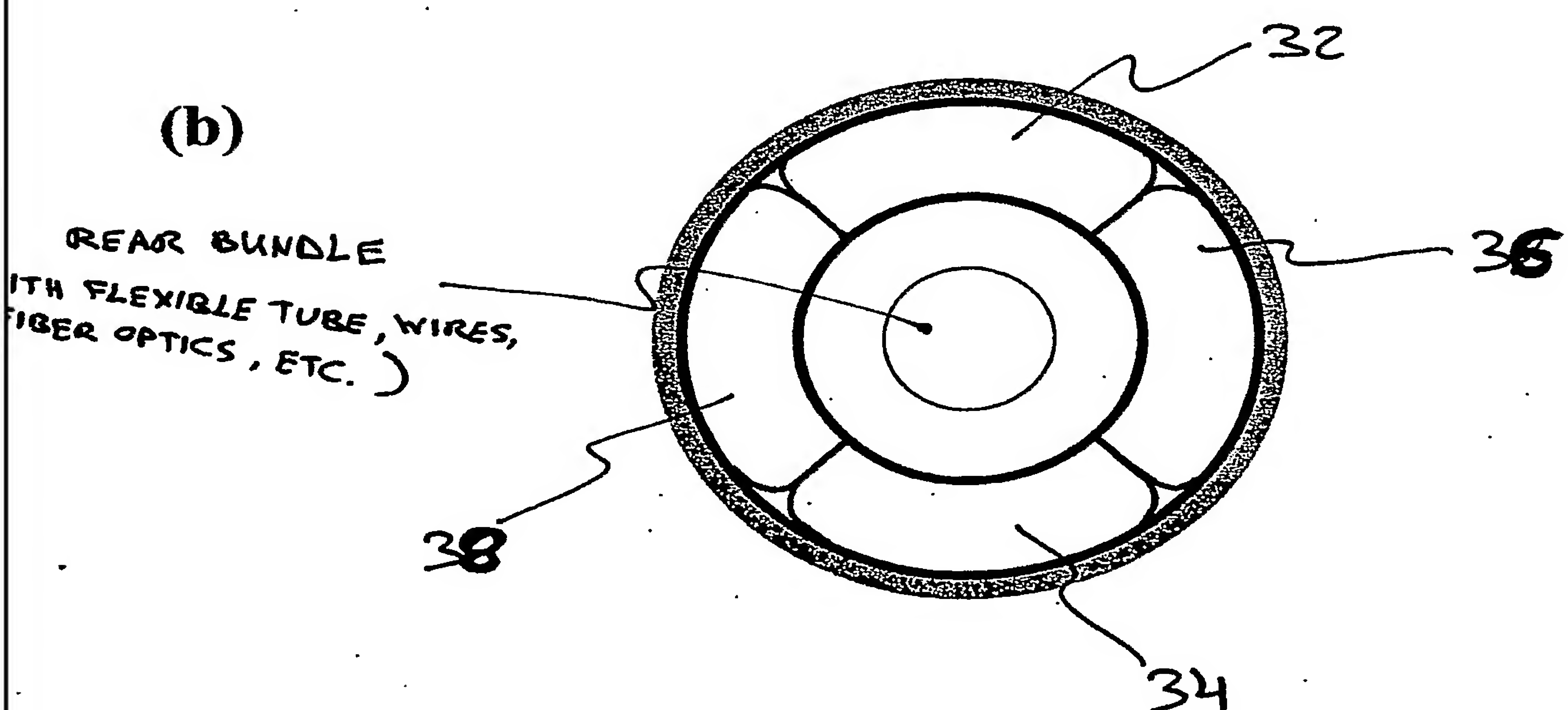
Fig.1:

(a)



22
INTESTINE'S INTERNAL WALL
INTESTINE'S WALL
28
MR CONCENTRIC HOLLOW TUBE
LED
CCD
MR HEAD
26
24

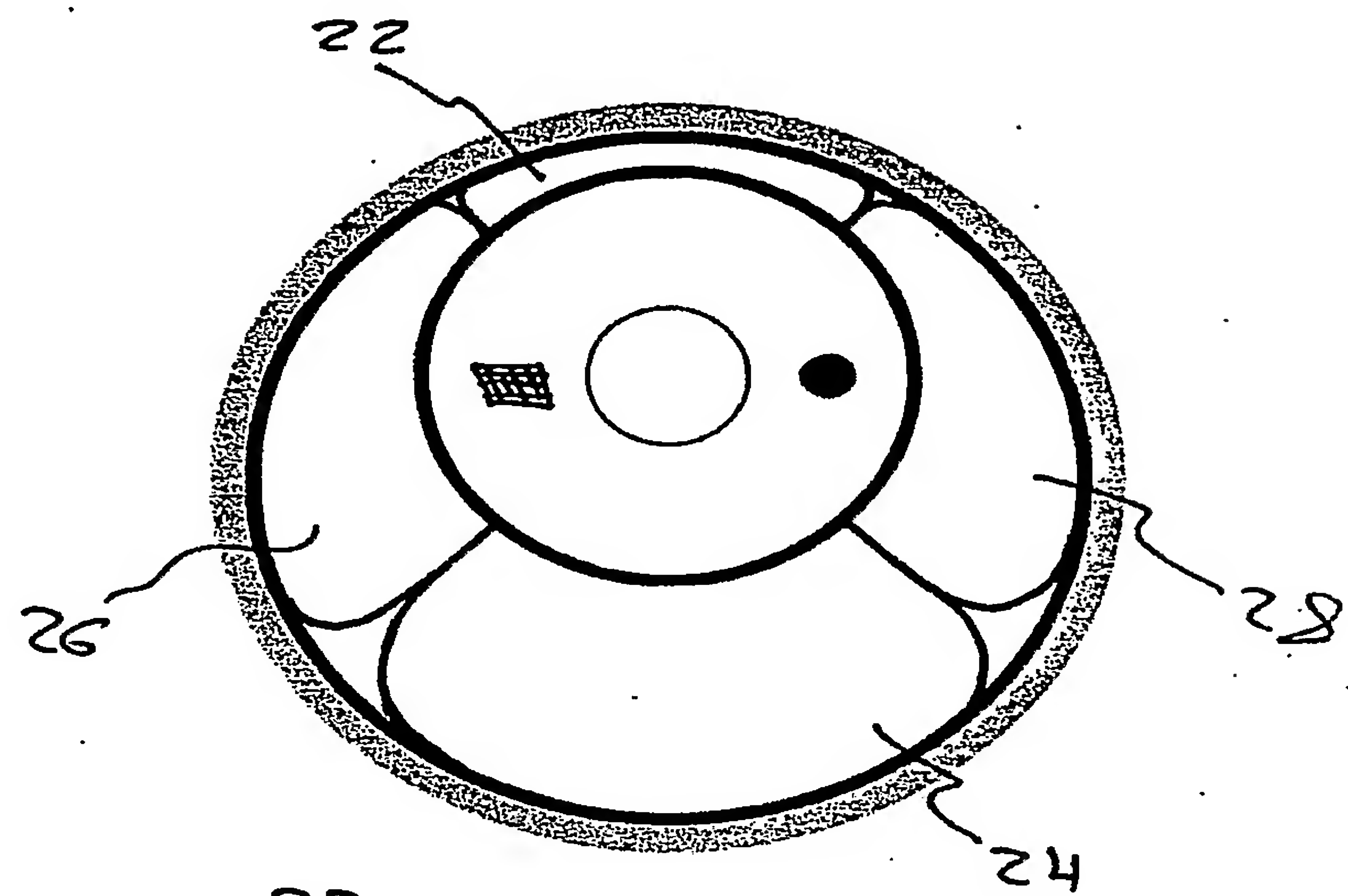
(b)



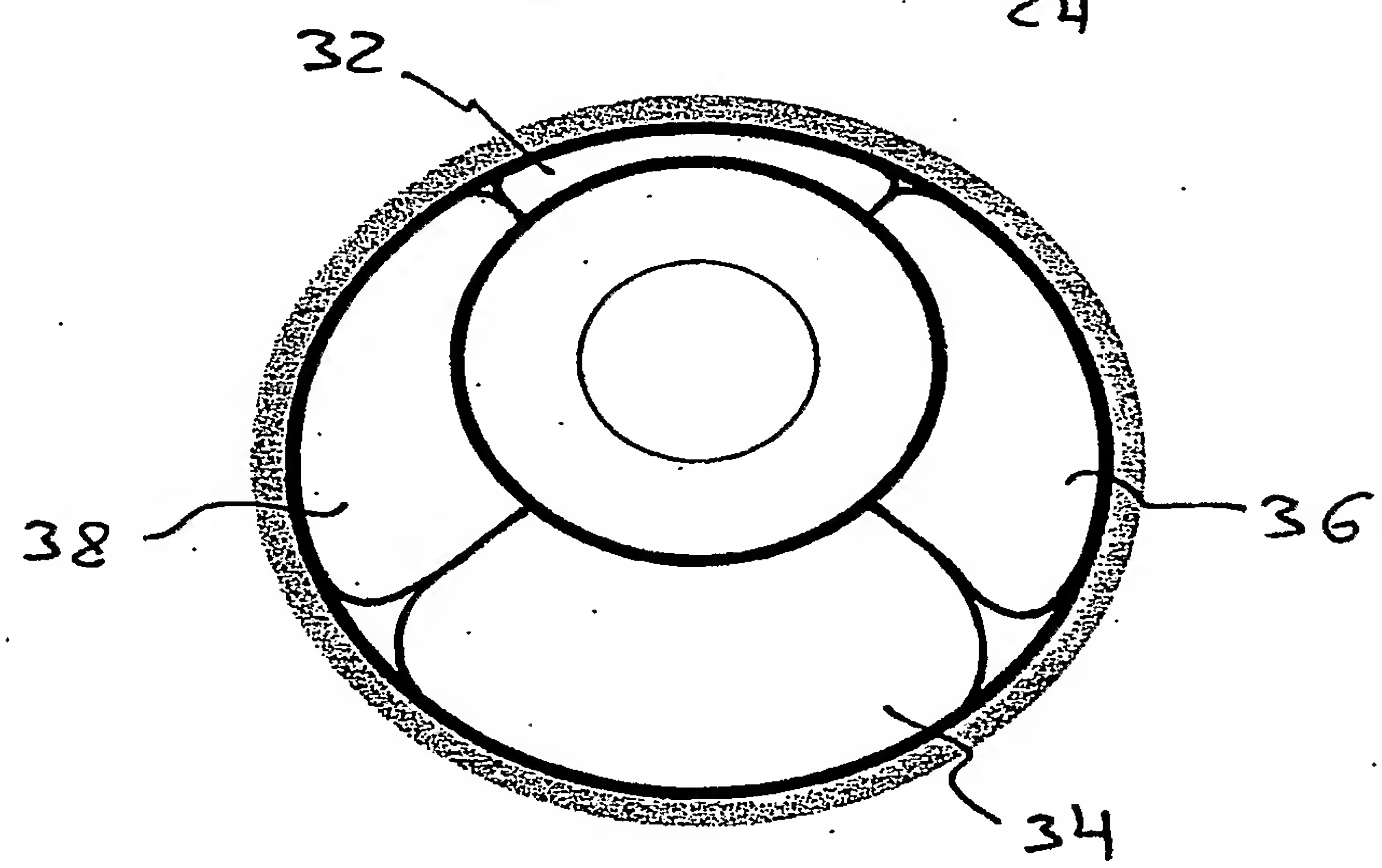
32
REAR BUNDLE
(WITH FLEXIBLE TUBE, WIRES, FIBER OPTICS, ETC.)
36
38
34

Fig.2:

(a)



(b)



(c)

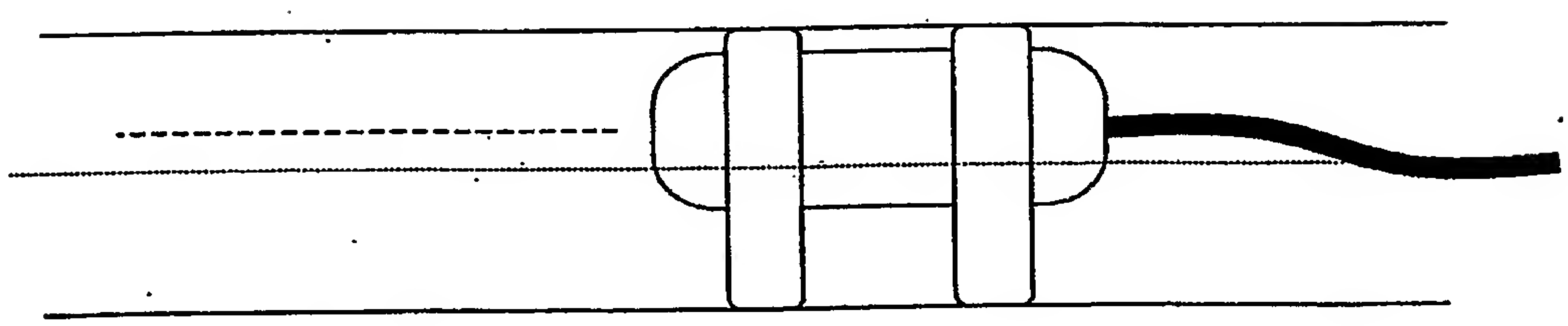
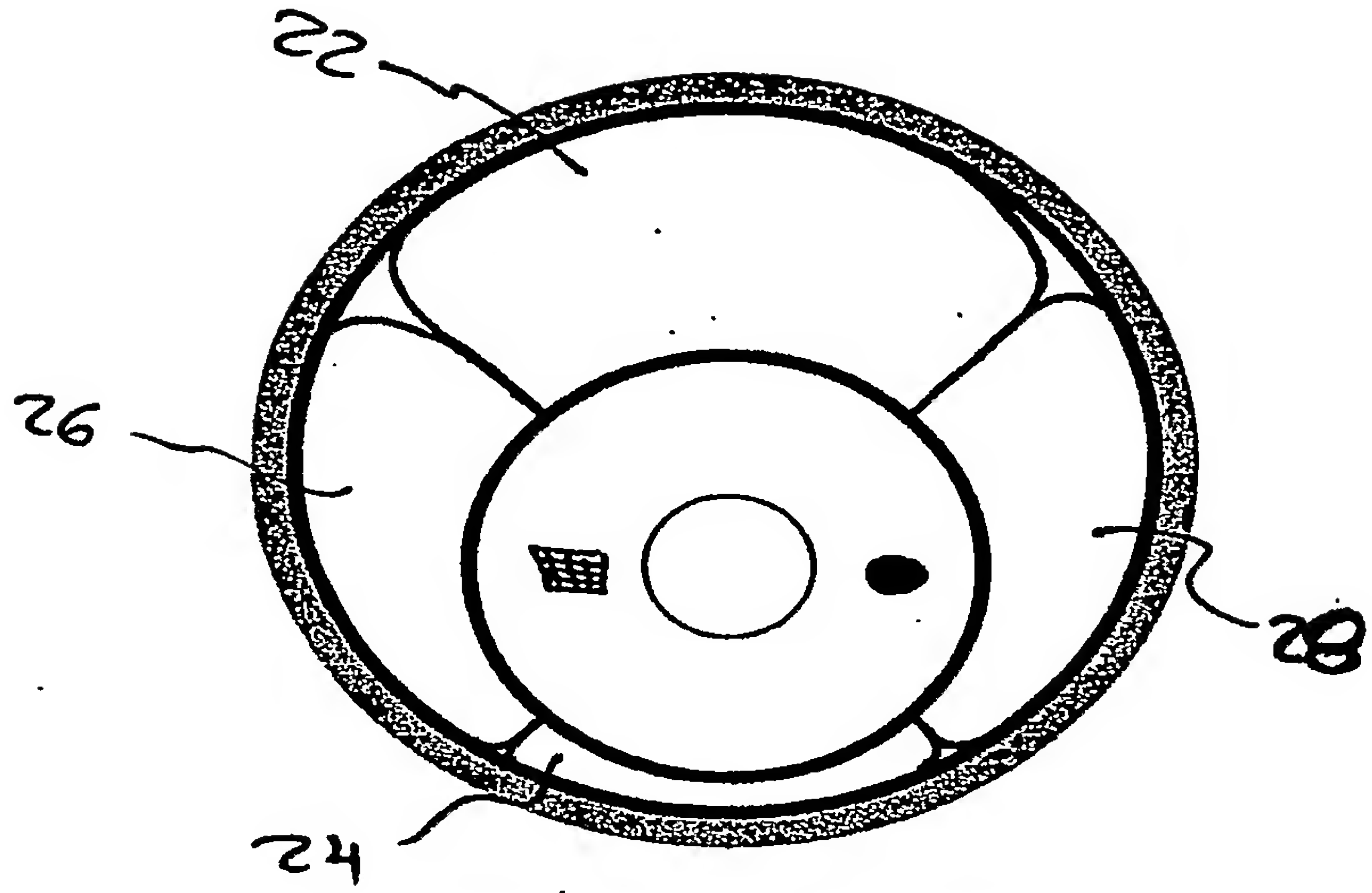
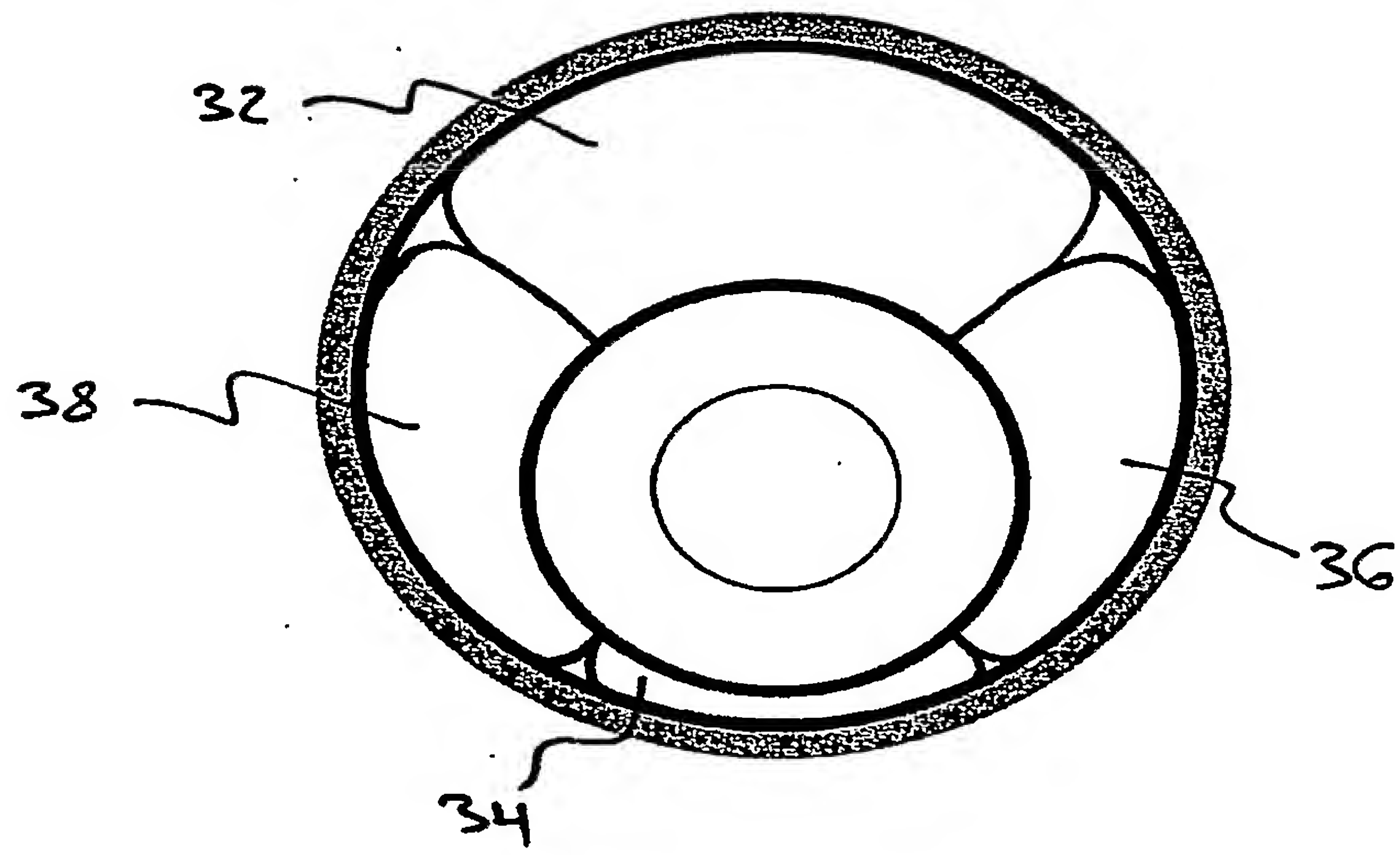


Fig.3:

(a)



(b)



(c)

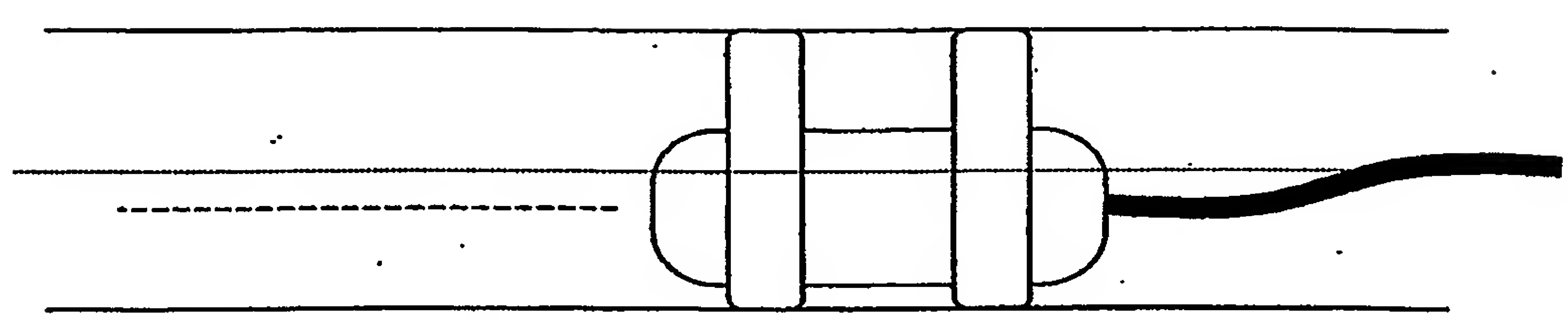


Fig.4:

(a)

(b)

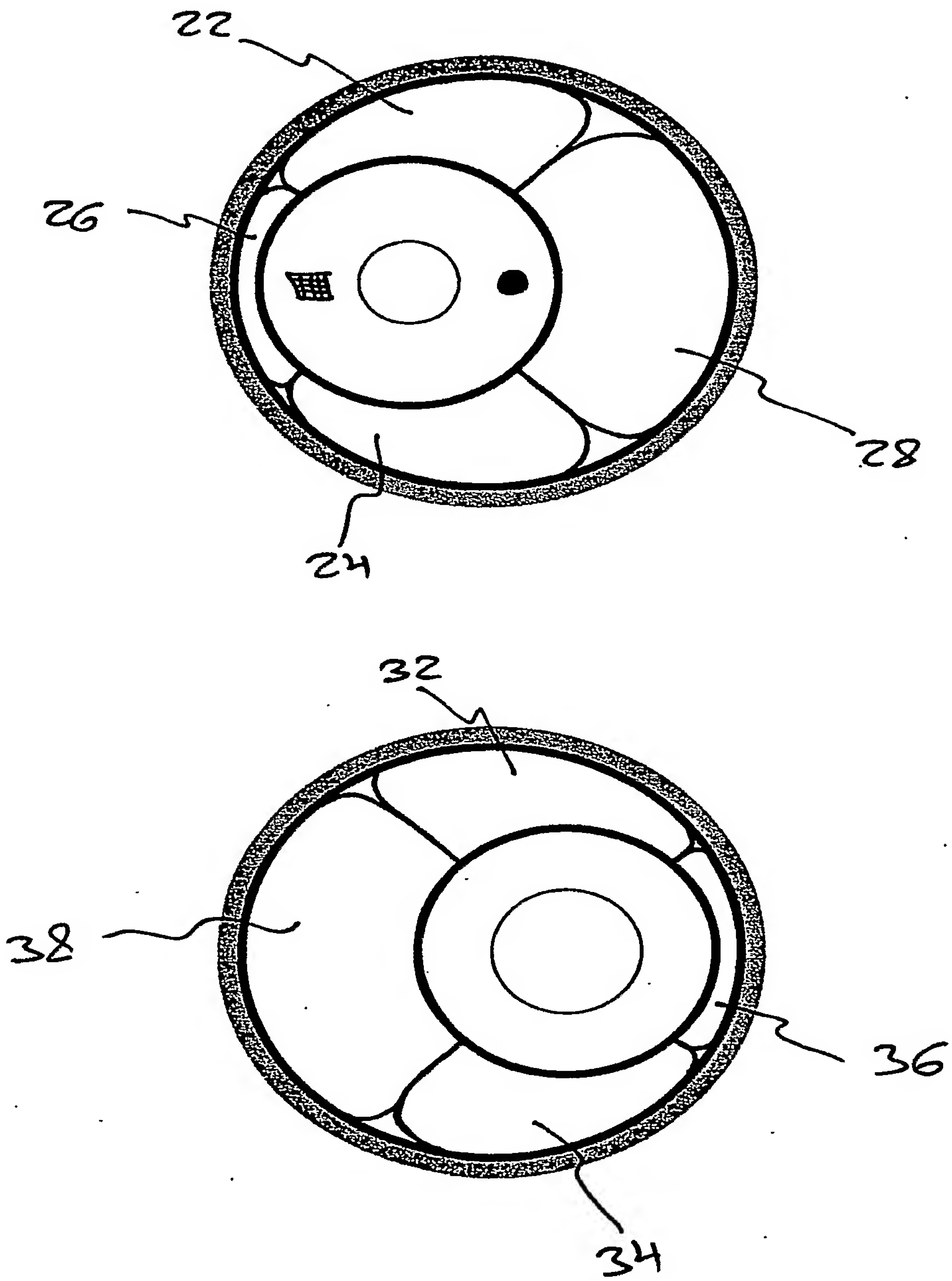


Fig.5:

(a)

(b)

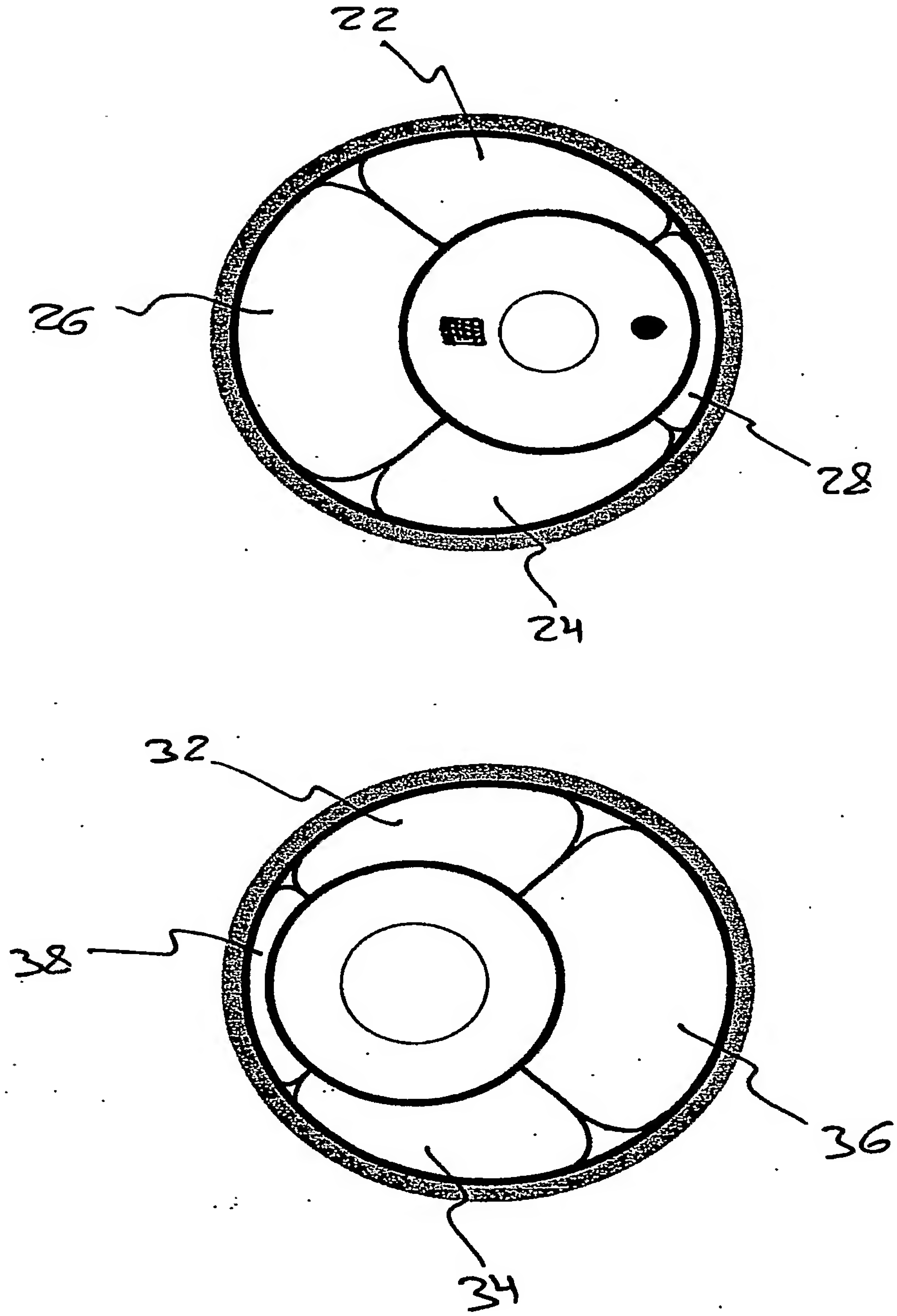
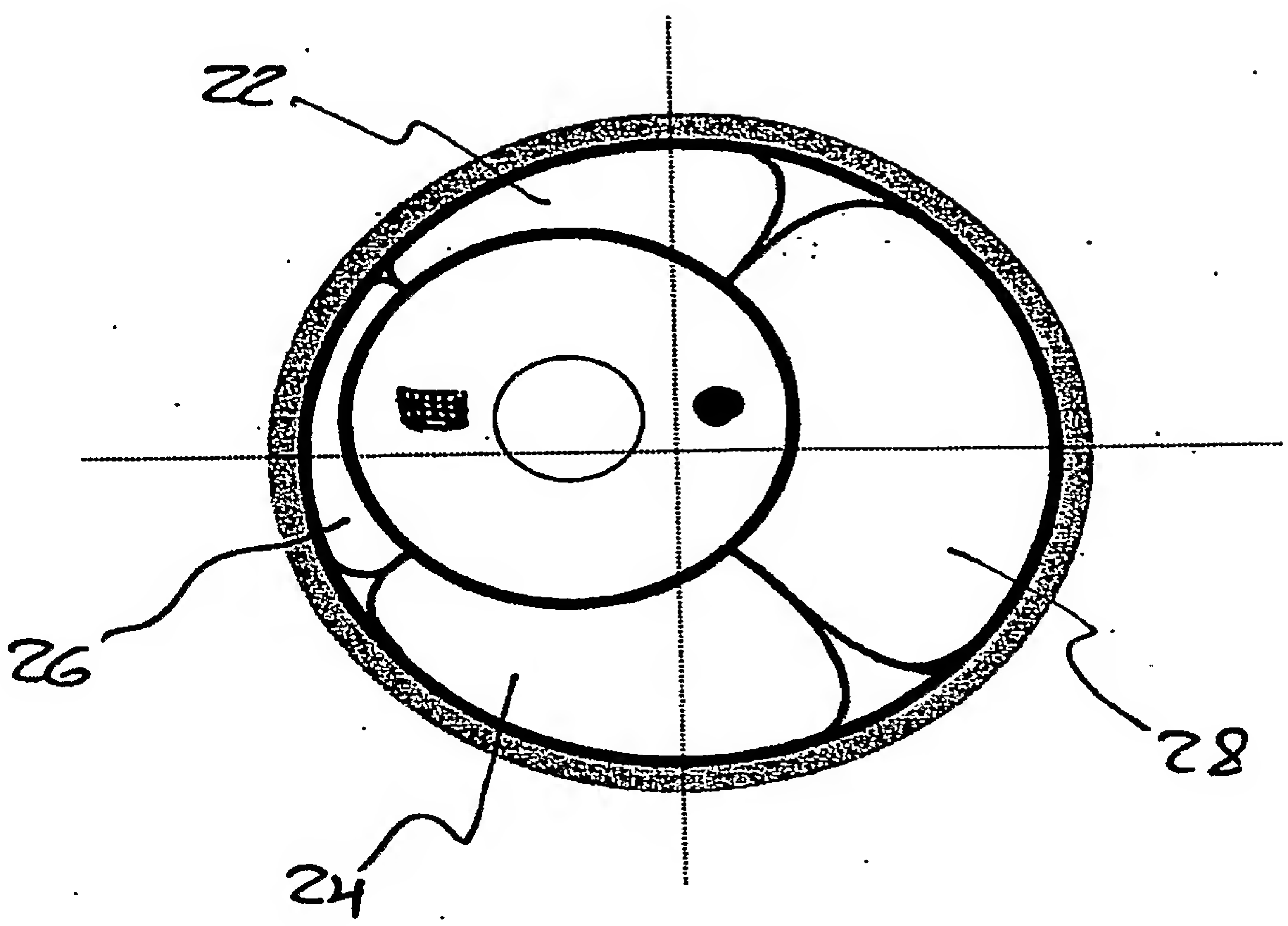


Fig.6:

(a)



(b)

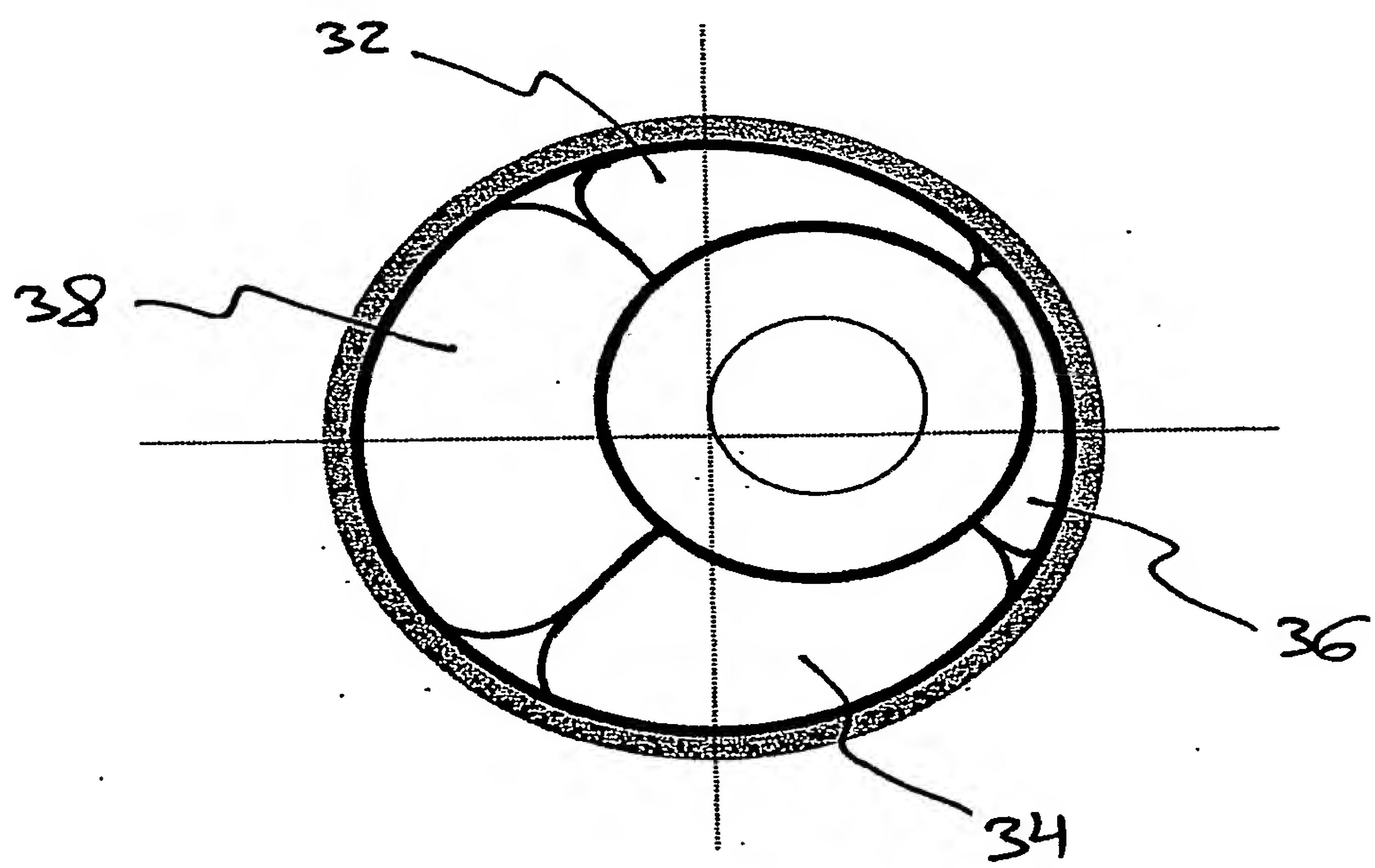
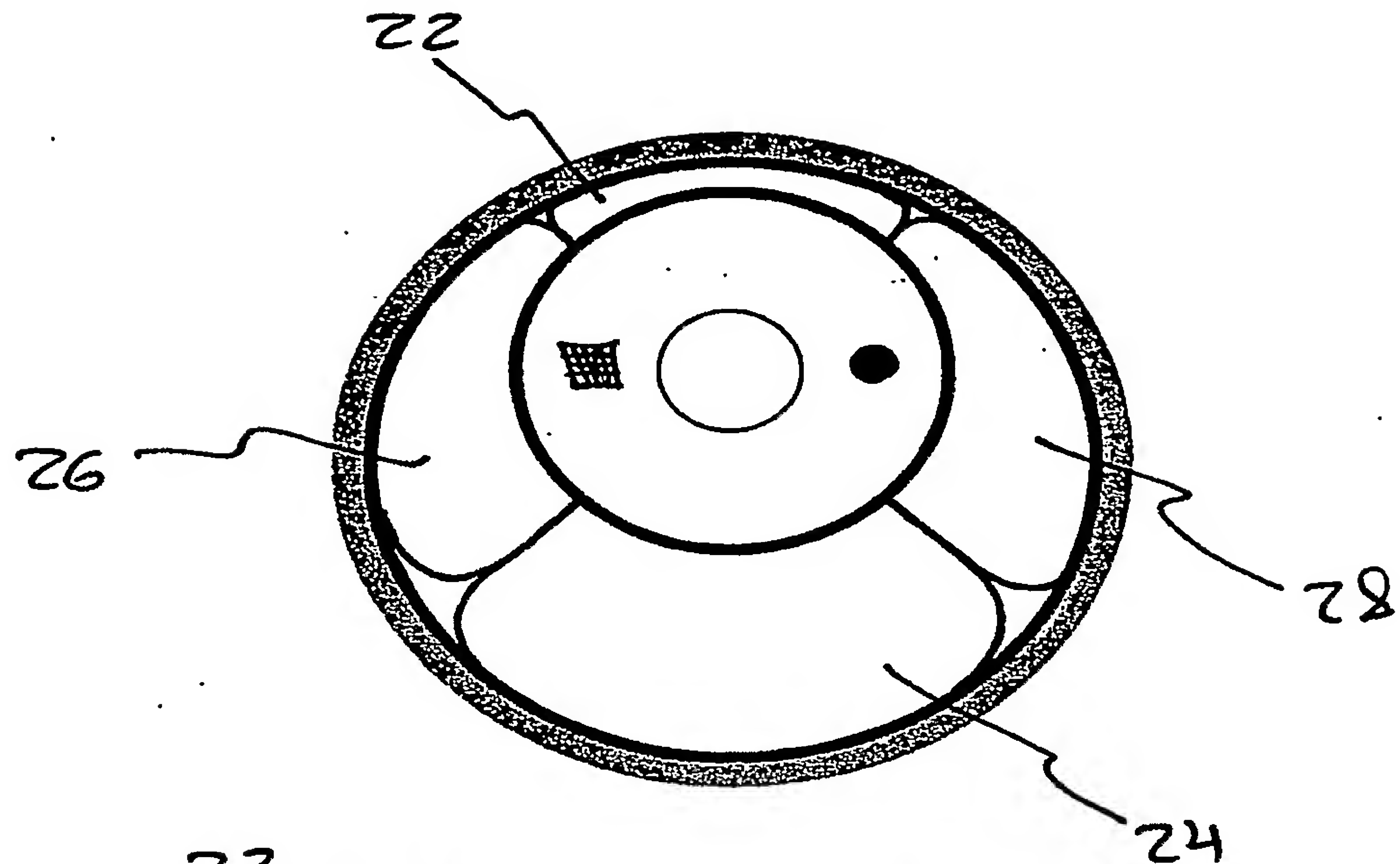
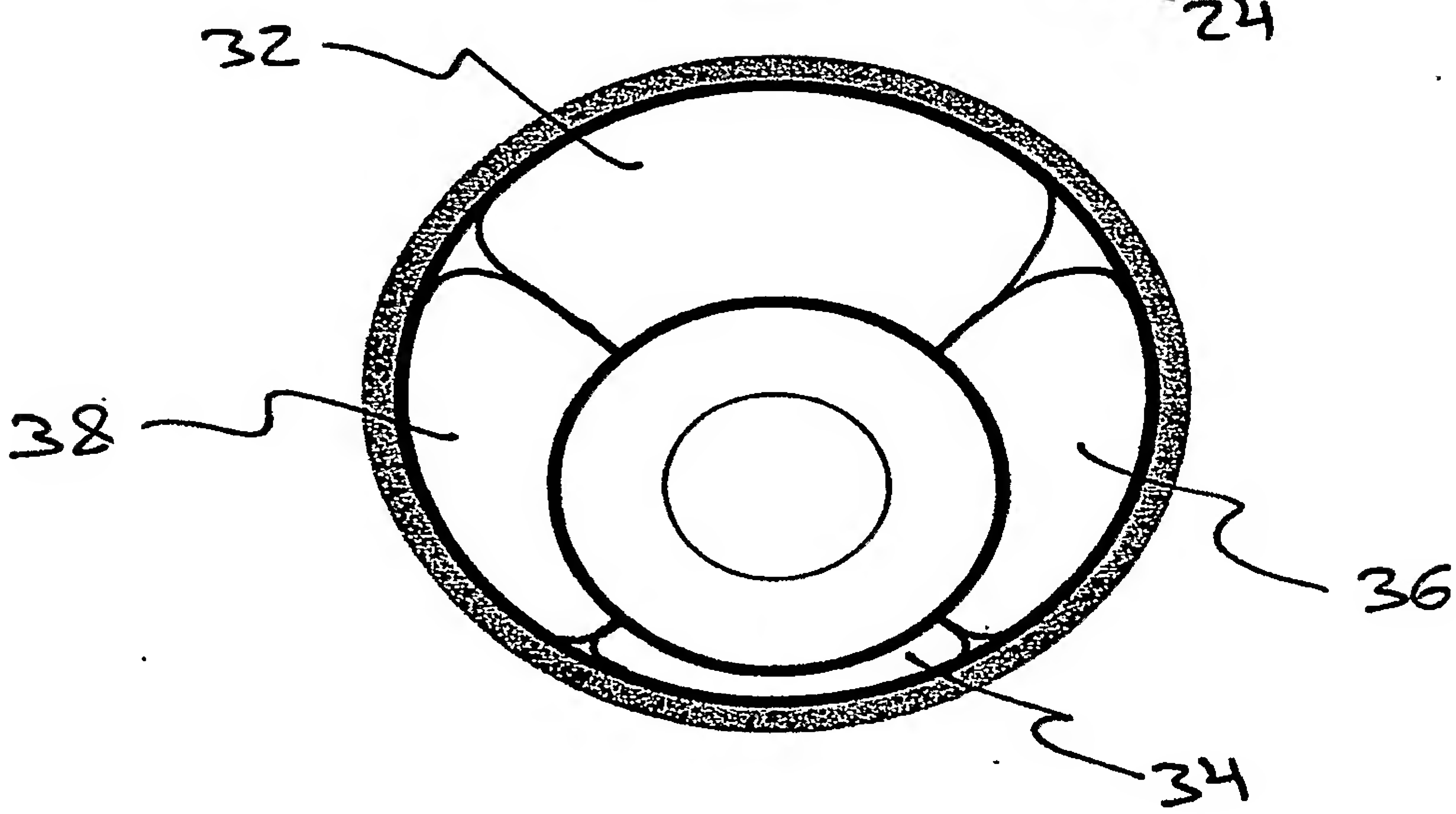


Fig.7:

(a)



(b)



(c)

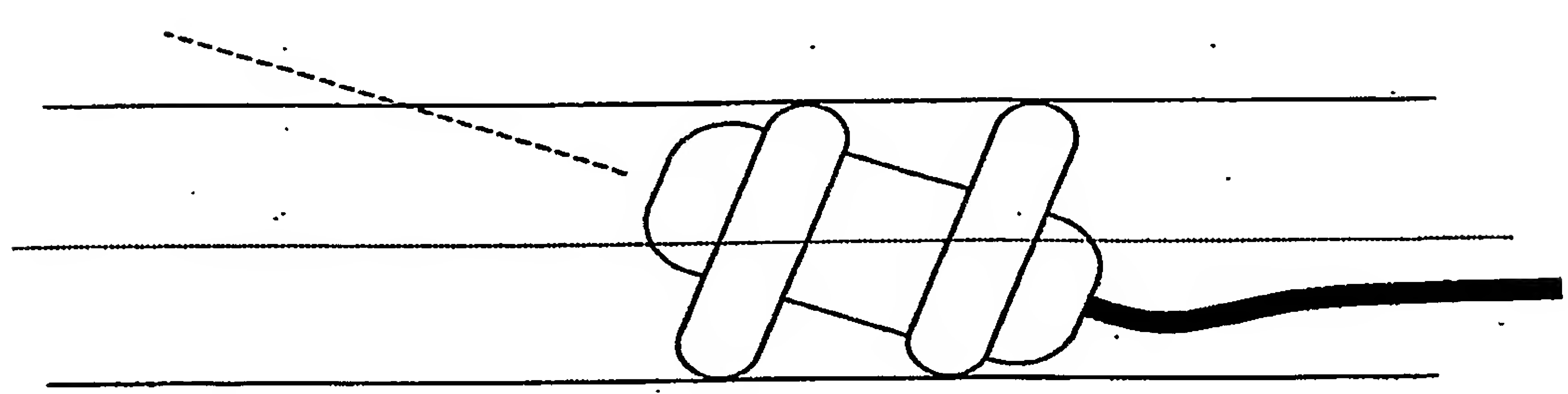


Fig.8:

(a)

(b)

(c)

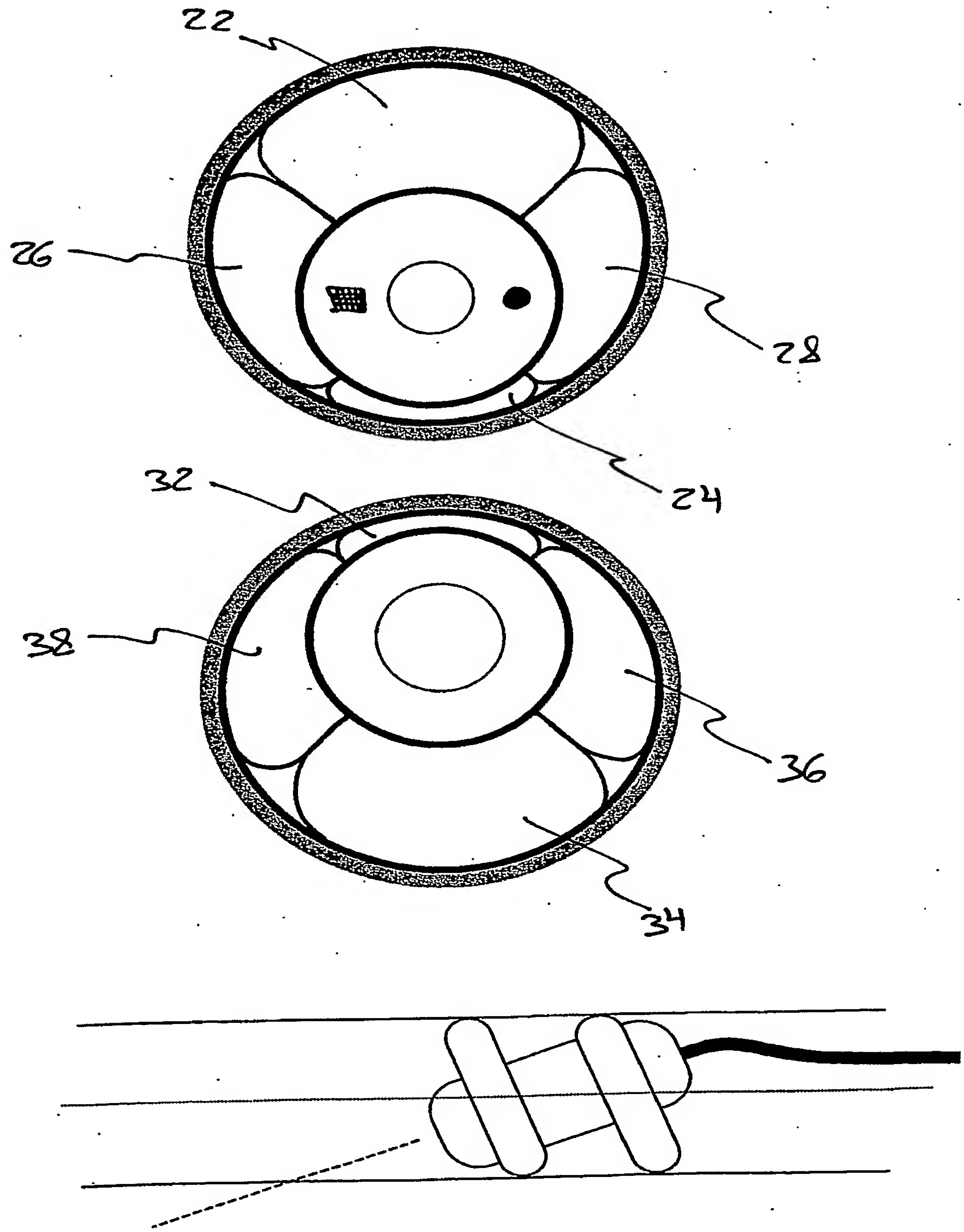
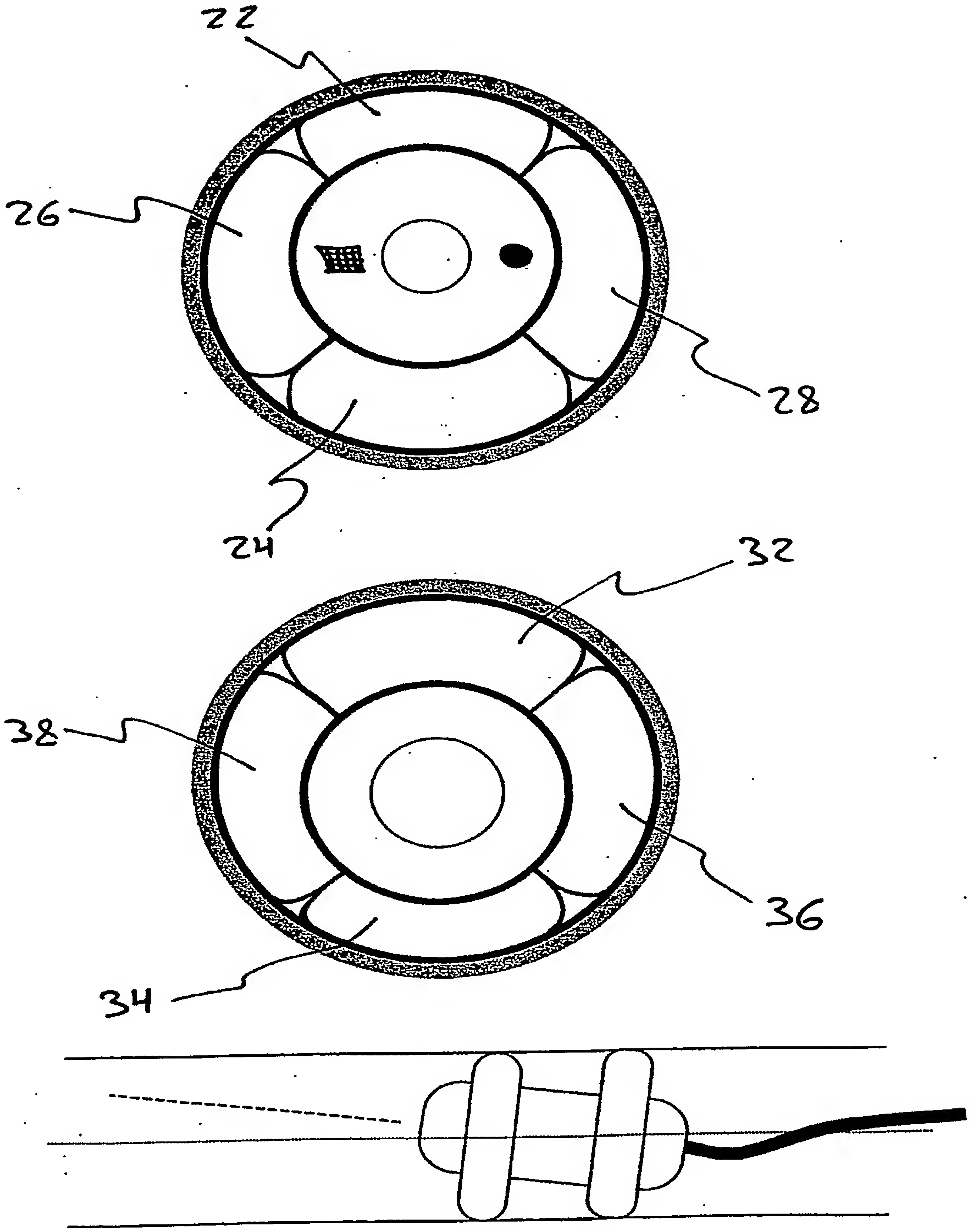


Fig.9:

(a)

(b)

(c)



ig. 10

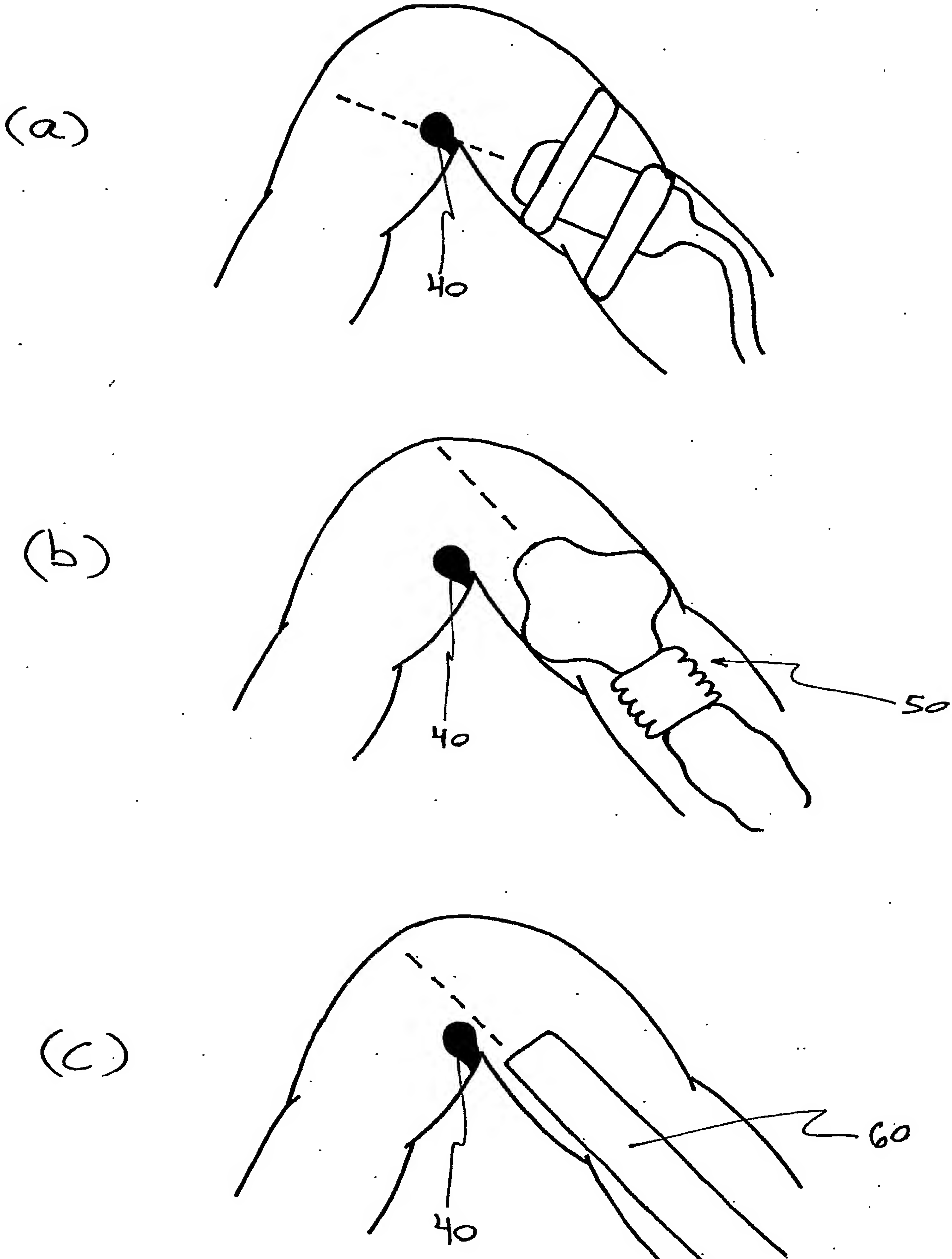
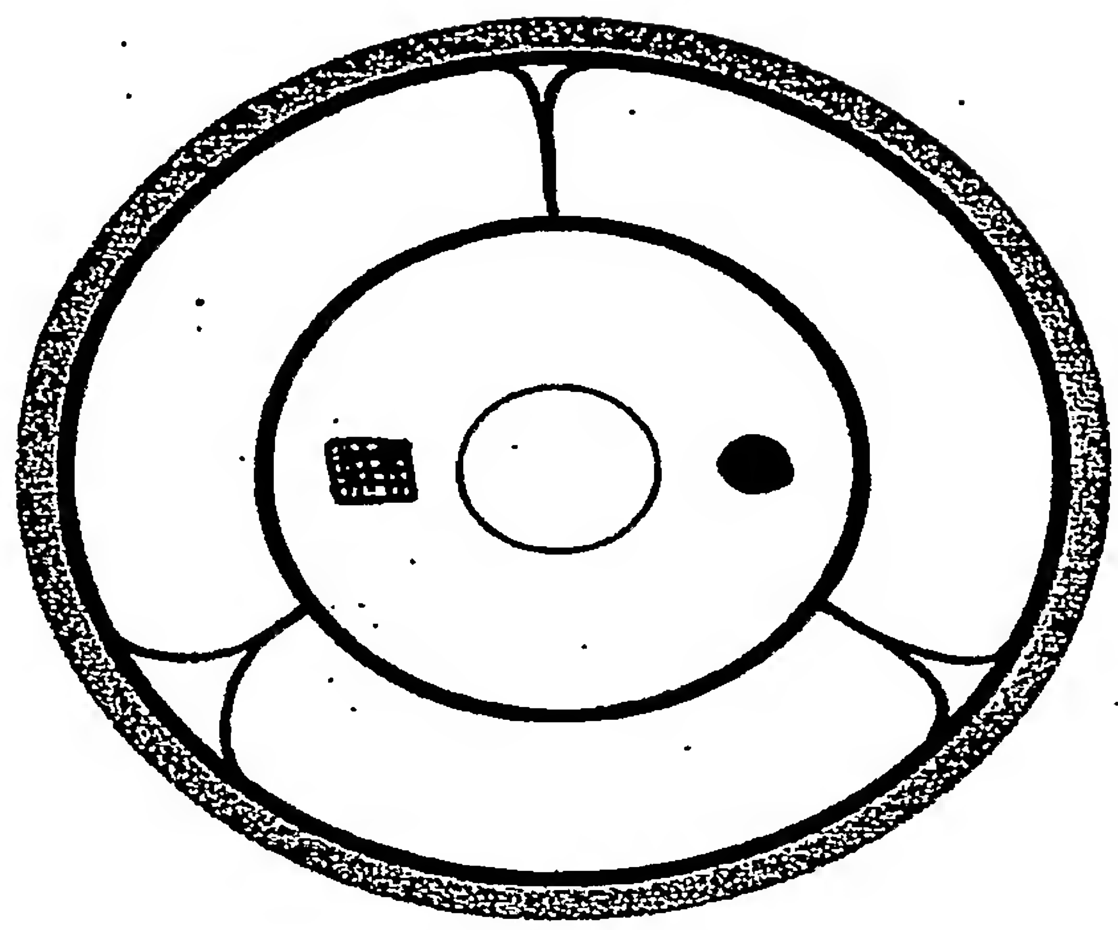


Fig.11:

(a)



(b)

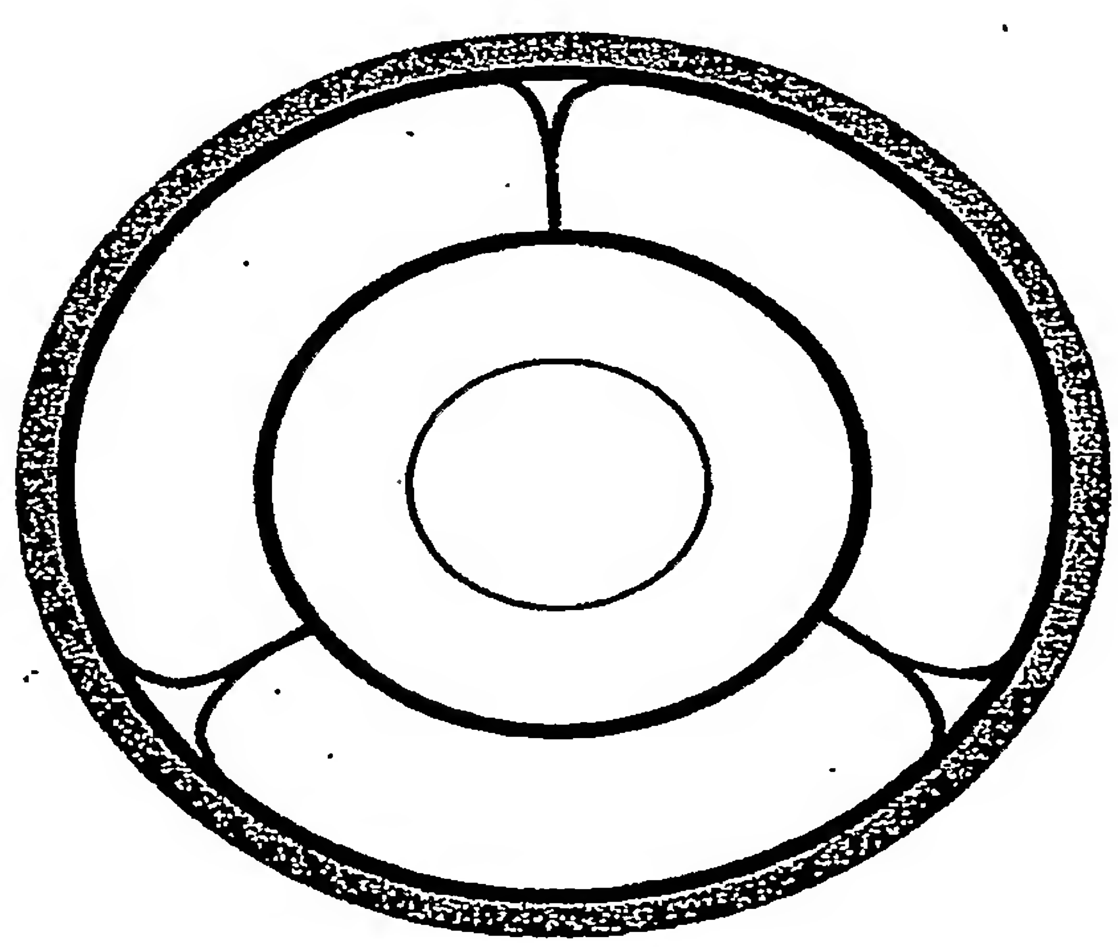
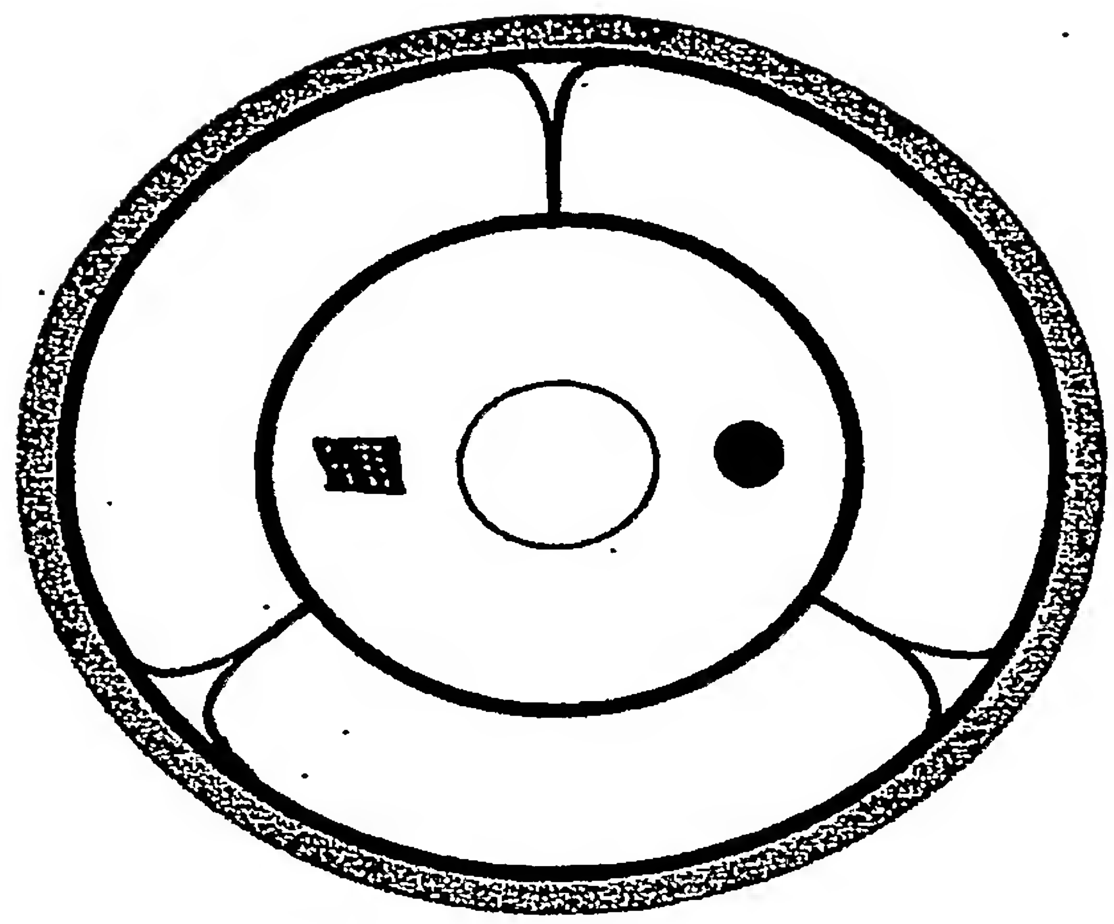


Fig.12:

(a)



(b)

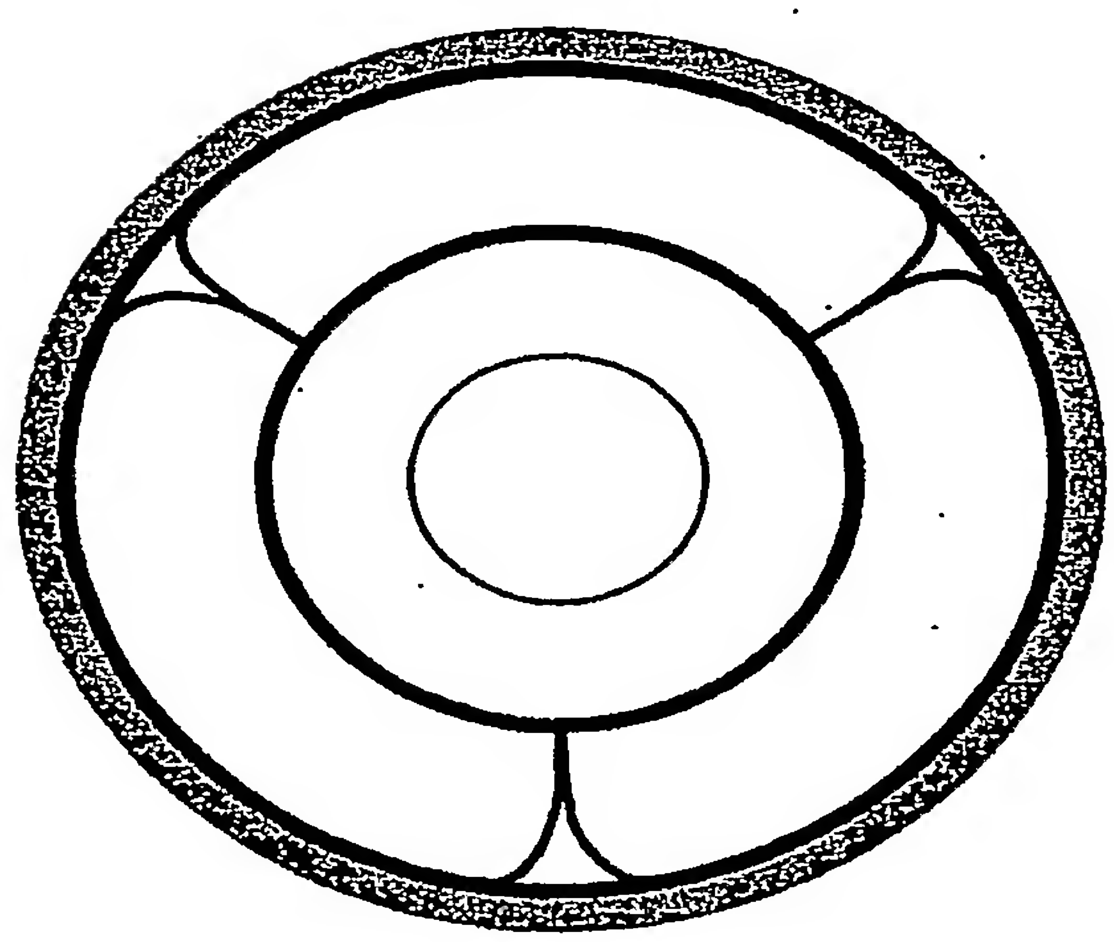
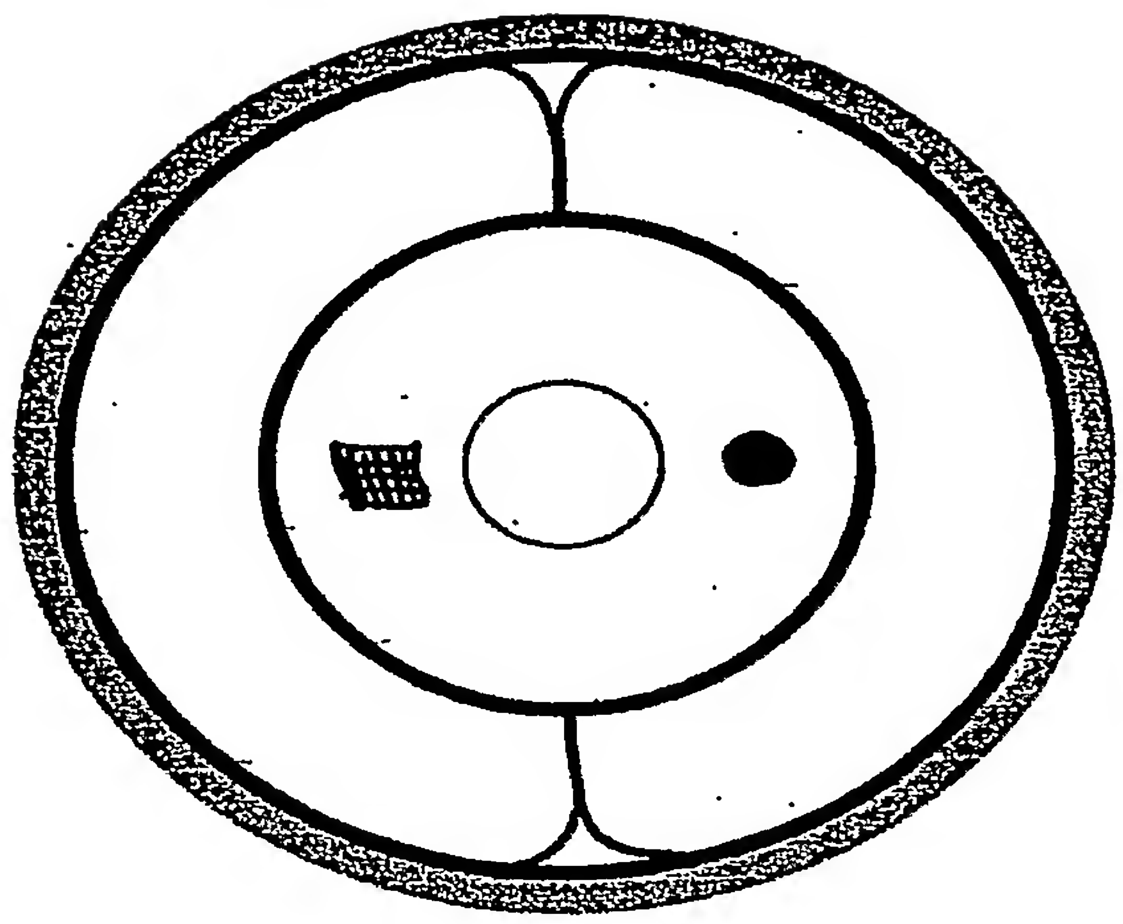


Fig.13:

(a)



(b)

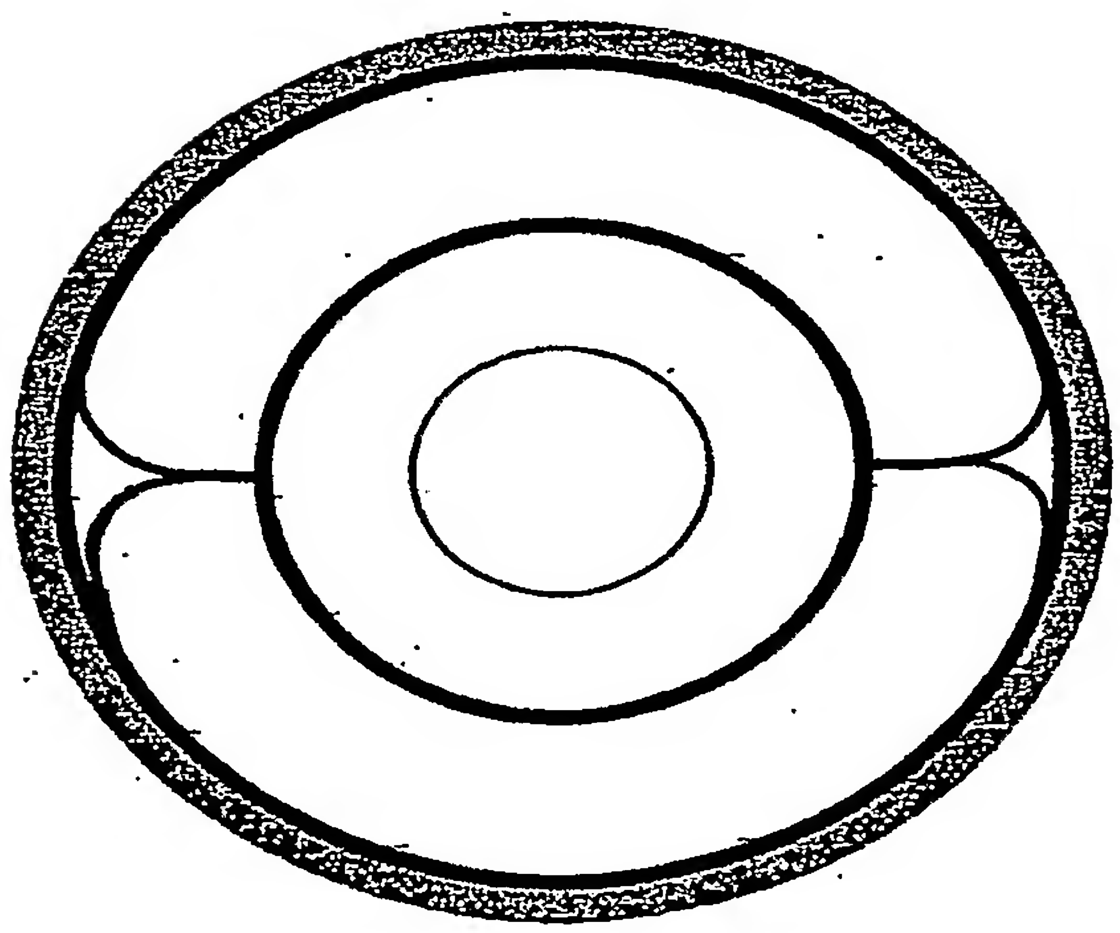


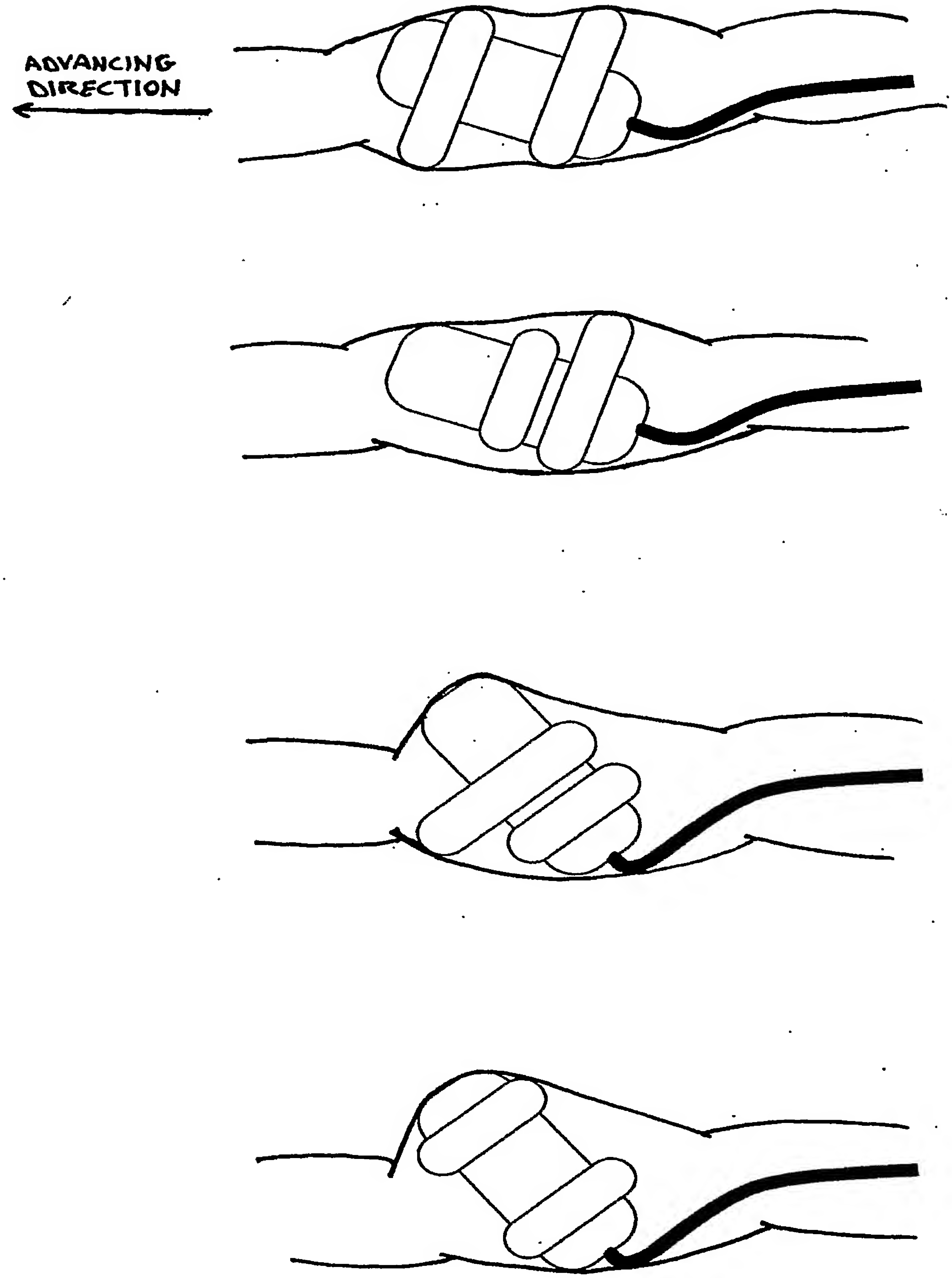
Fig.14:

(a)

(b)

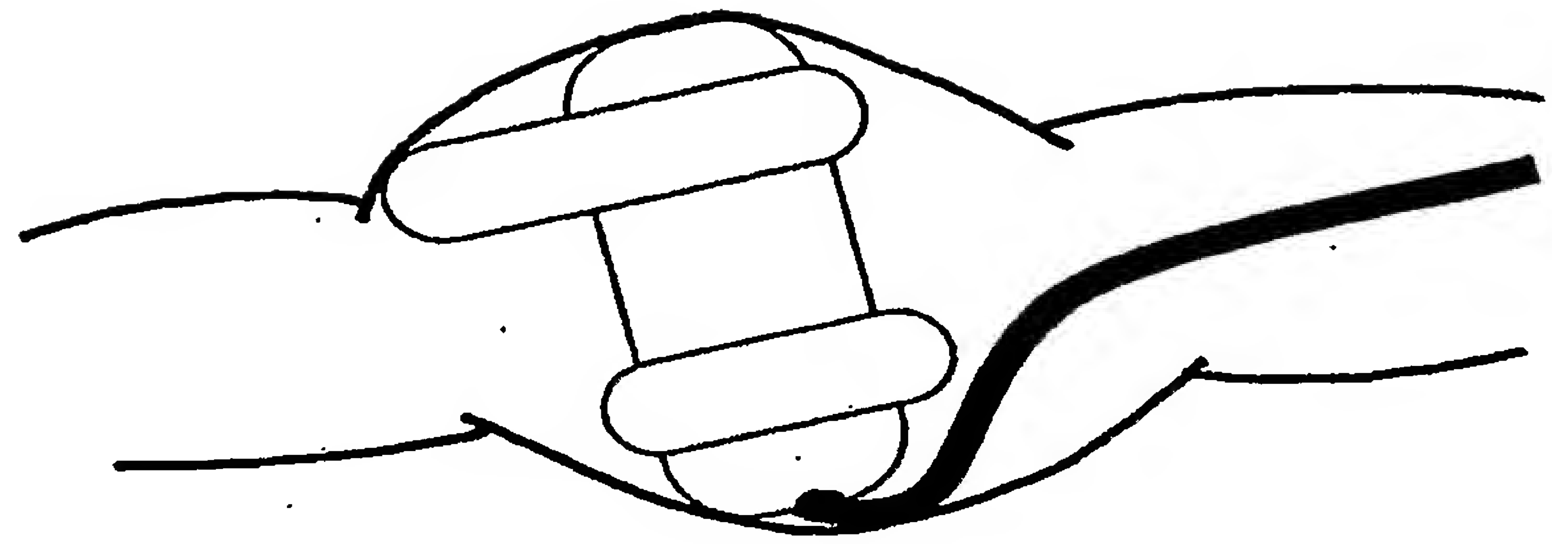
(c)

(d)

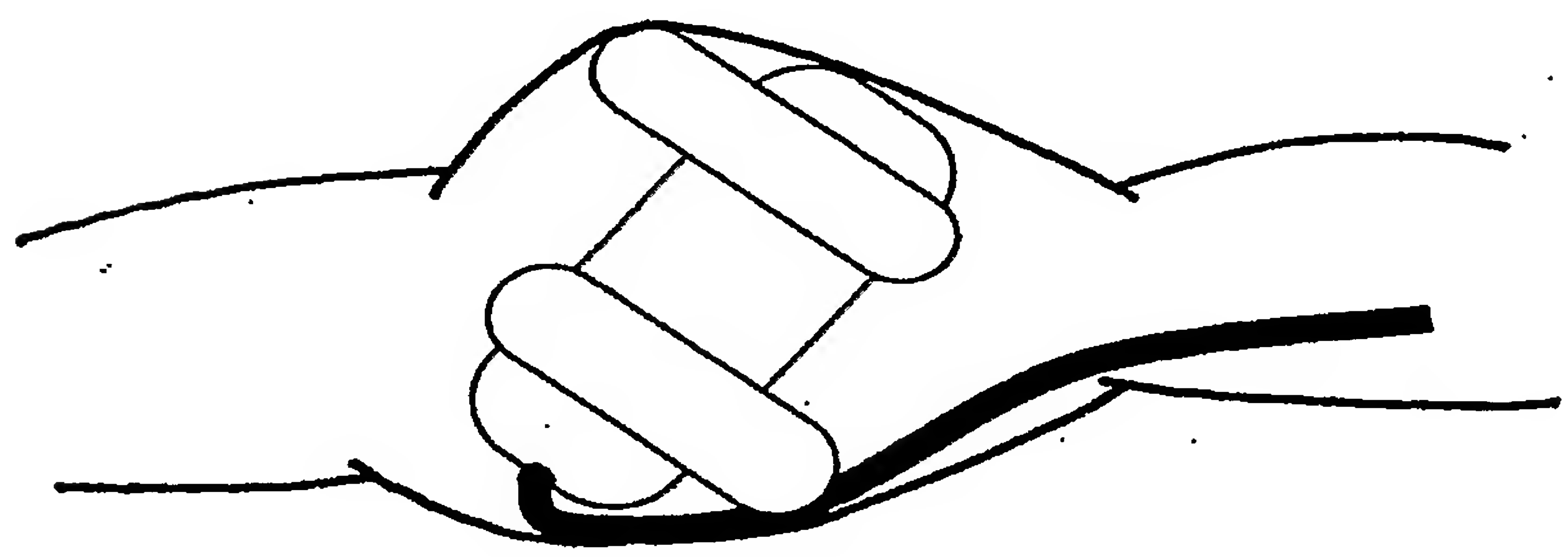


g.14 (continue):

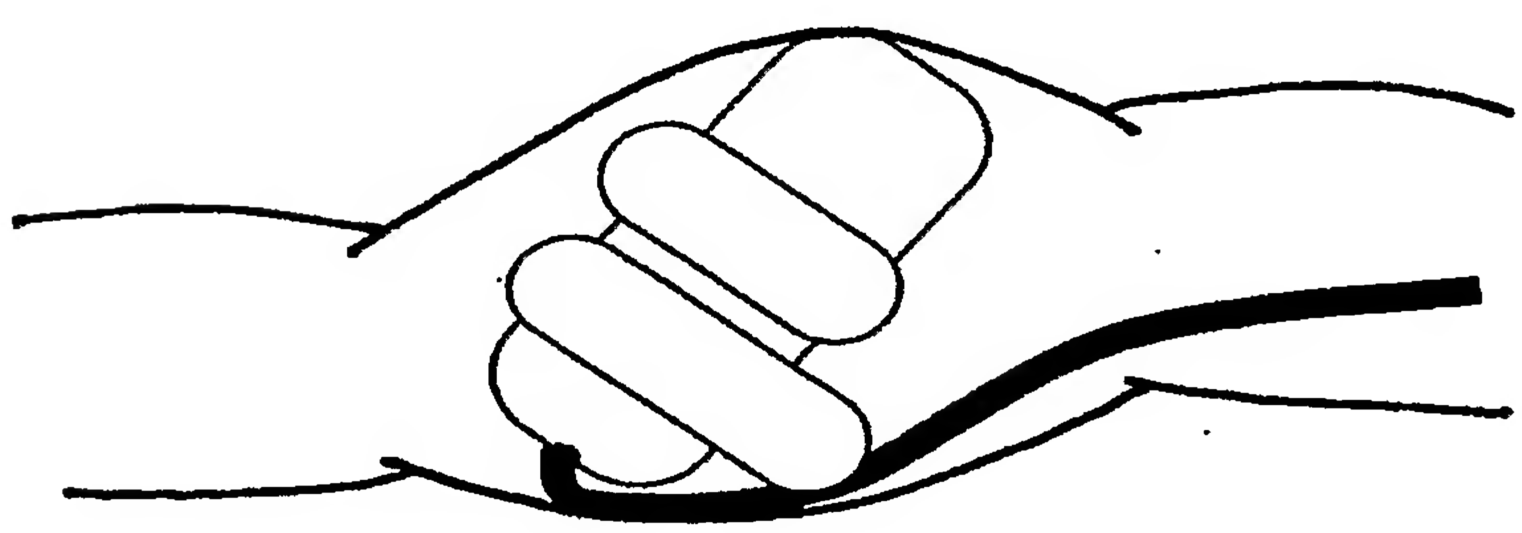
e)



(f)



(g)



(h)

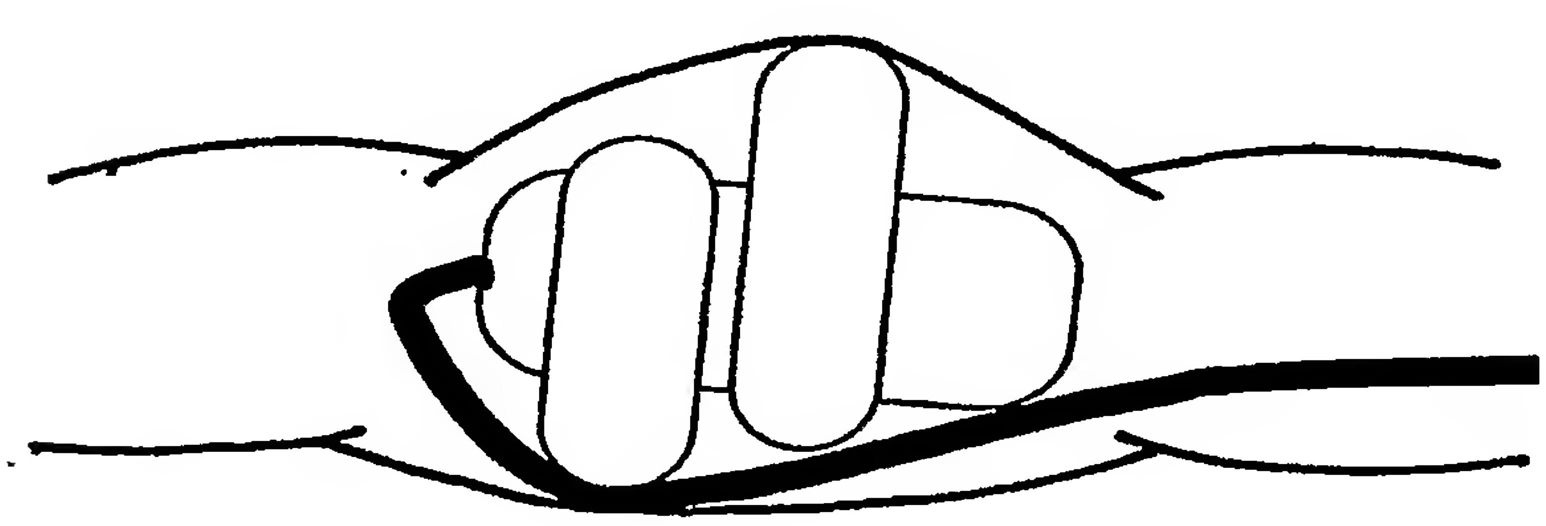


Fig.15:

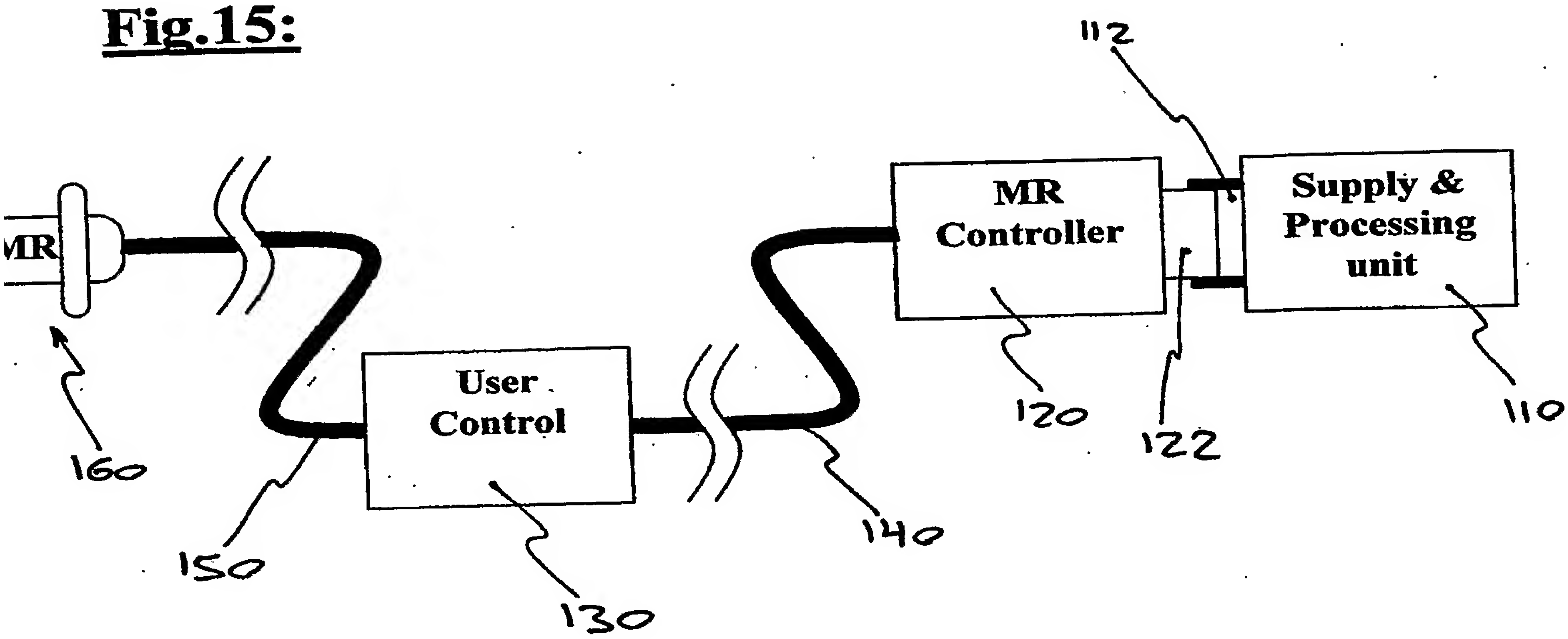

112
MR
Supply & Processing unit
MR Controller
User Control
160
150
130
140
120
122
110

Fig.16:

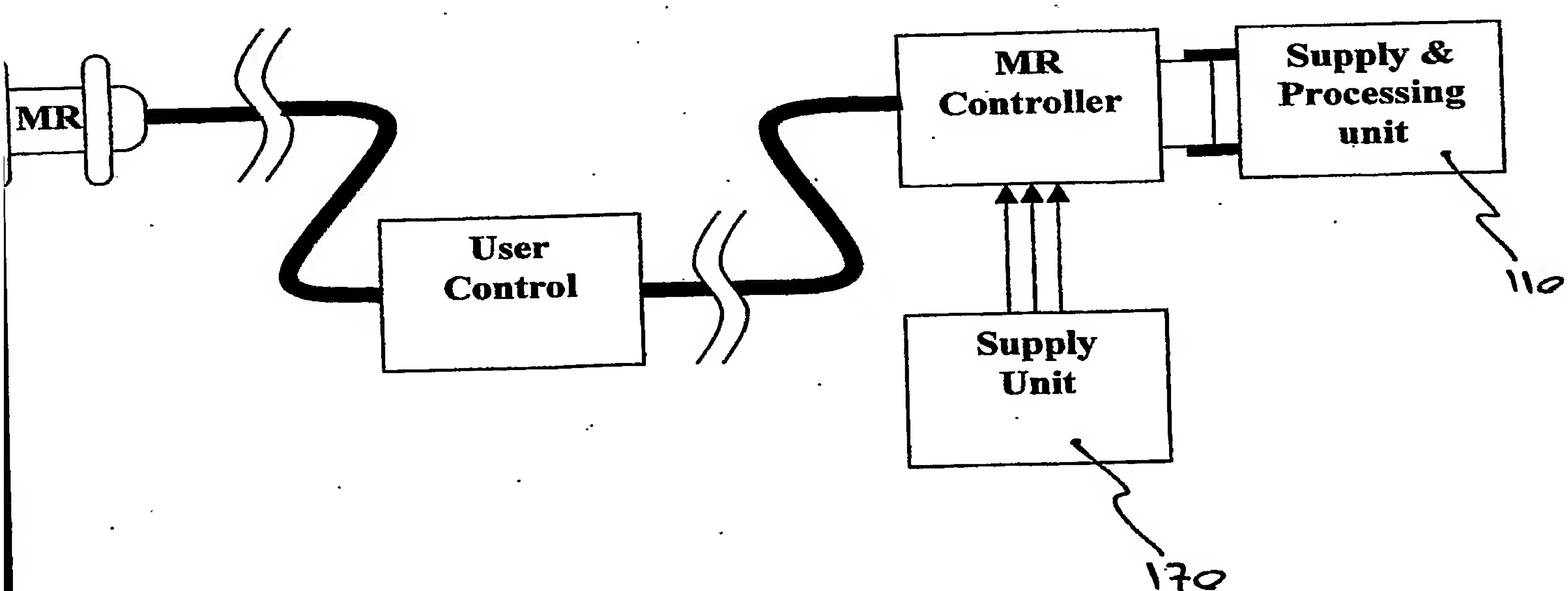
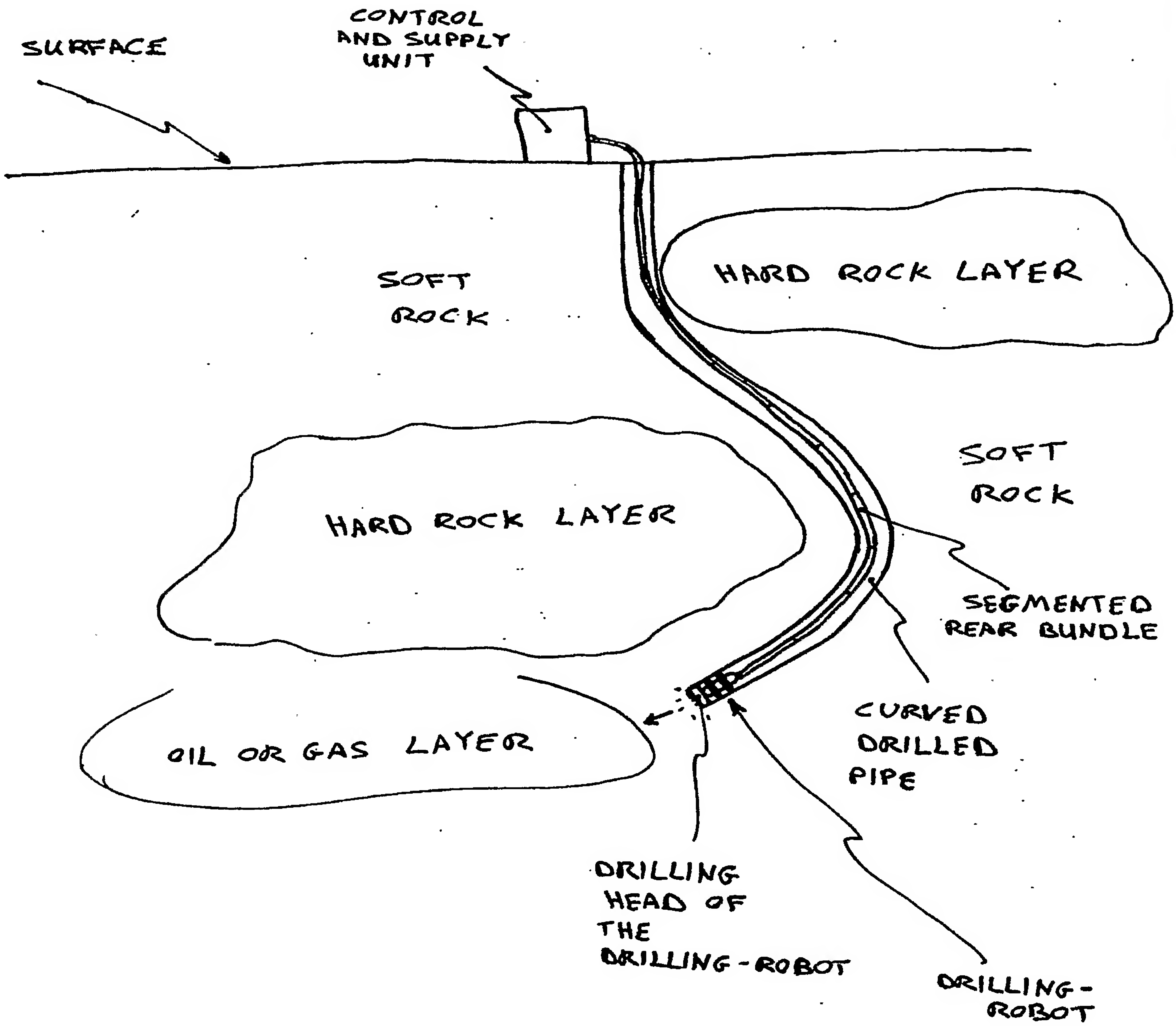
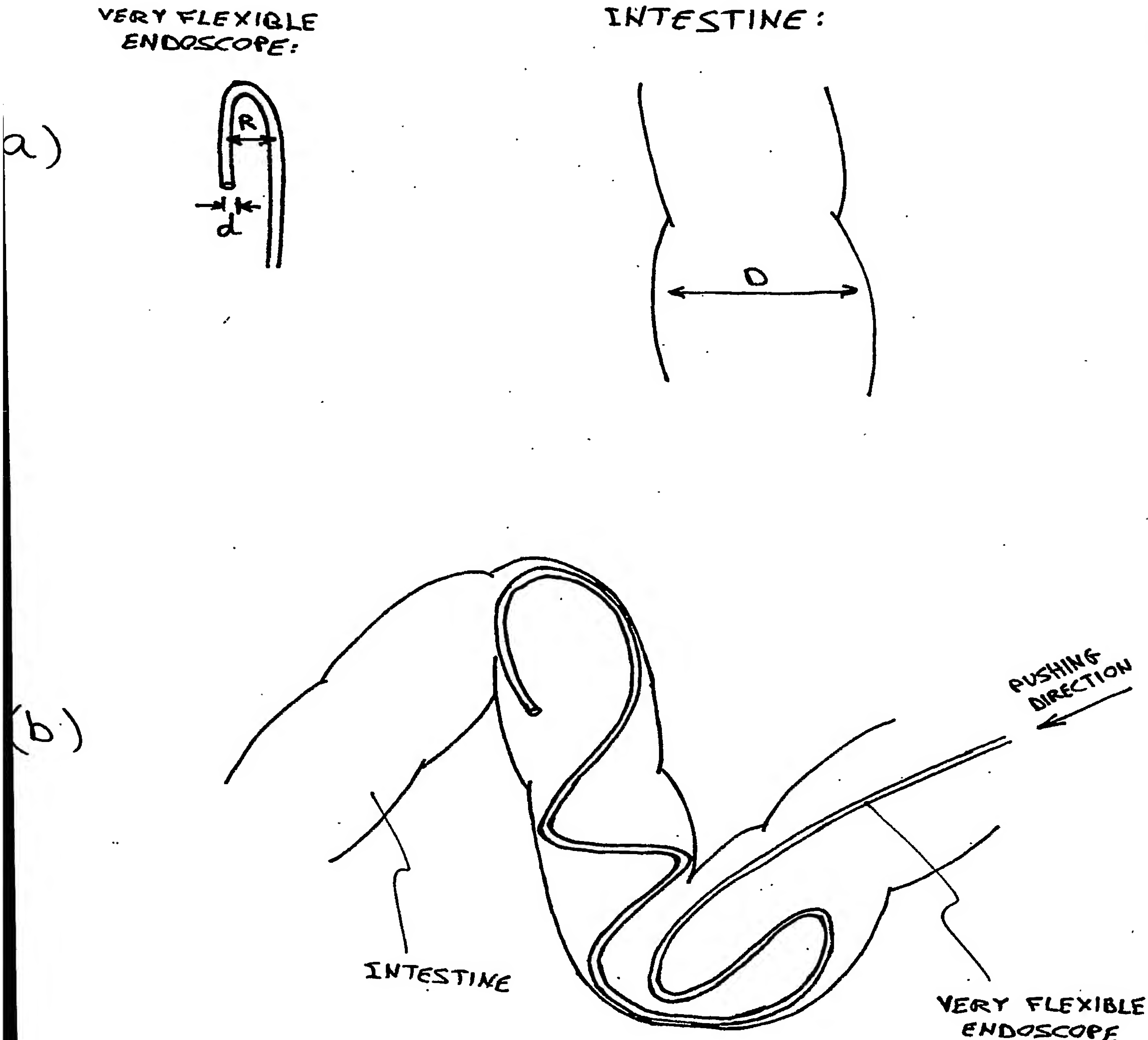

MR
MR Controller
Supply & Processing unit
User Control
Supply Unit
110
170

Fig. 17:



CONTROL AND SUPPLY UNIT
LAND SURFACE
SOFT ROCK
HARD ROCK LAYER
SOFT ROCK
HARD ROCK LAYER
SEGMENTED REAR BUNDLE
CURVED DRILLED PIPE
OIL OR GAS LAYER
DRILLING HEAD OF THE DRILLING-ROBOT
DRILLING-ROBOT

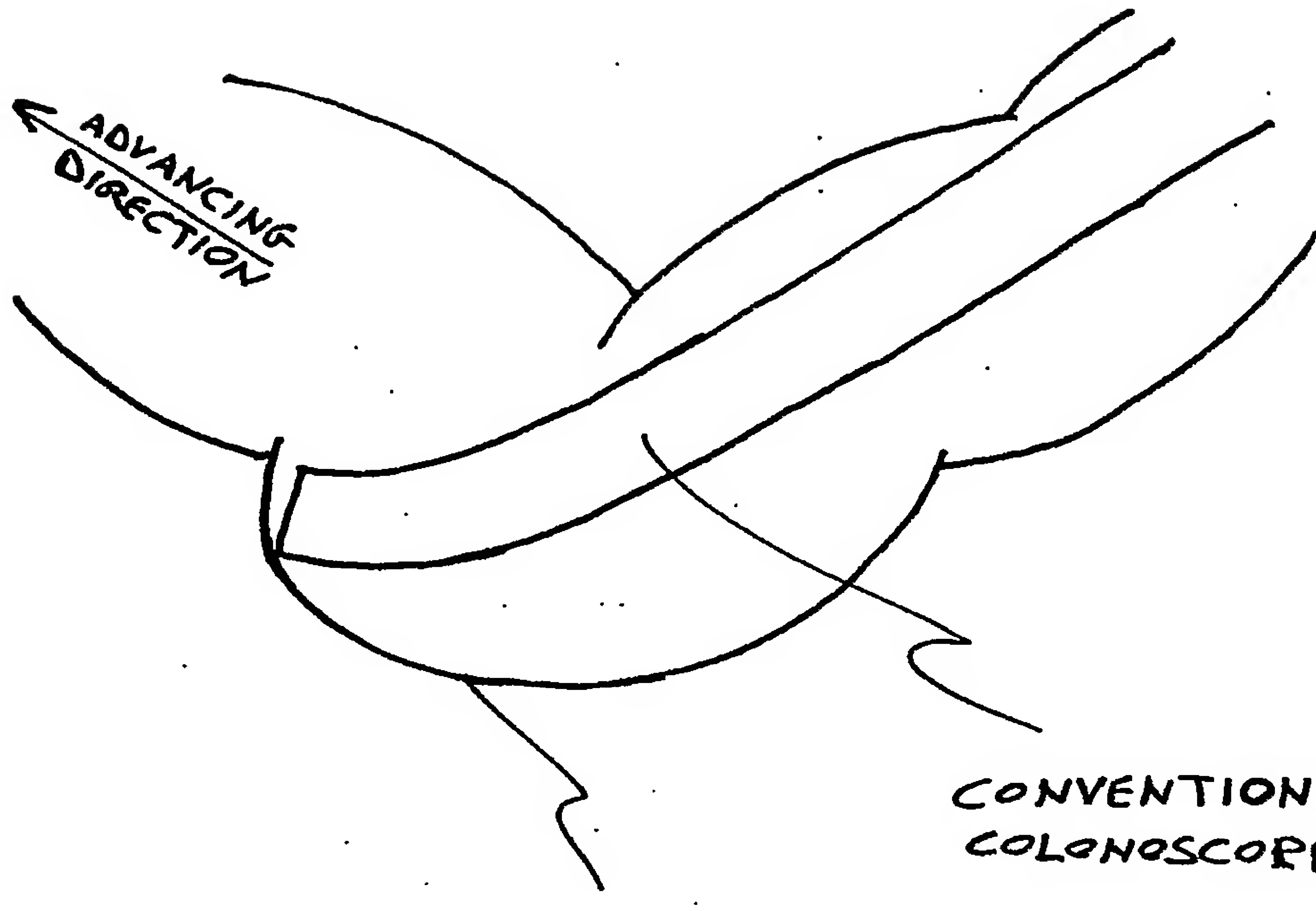
ig. 18 :



VERY FLEXIBLE ENDOSCOPE:
INTESTINE:
a)
R
d
D
(b)
PUSHING DIRECTION
INTESTINE
VERY FLEXIBLE ENDOSCOPE

Fig. 19:

(a)



ADVANCING DIRECTION
CONVENTIONAL COLONOSCOPE
COLON WALLS

(b)

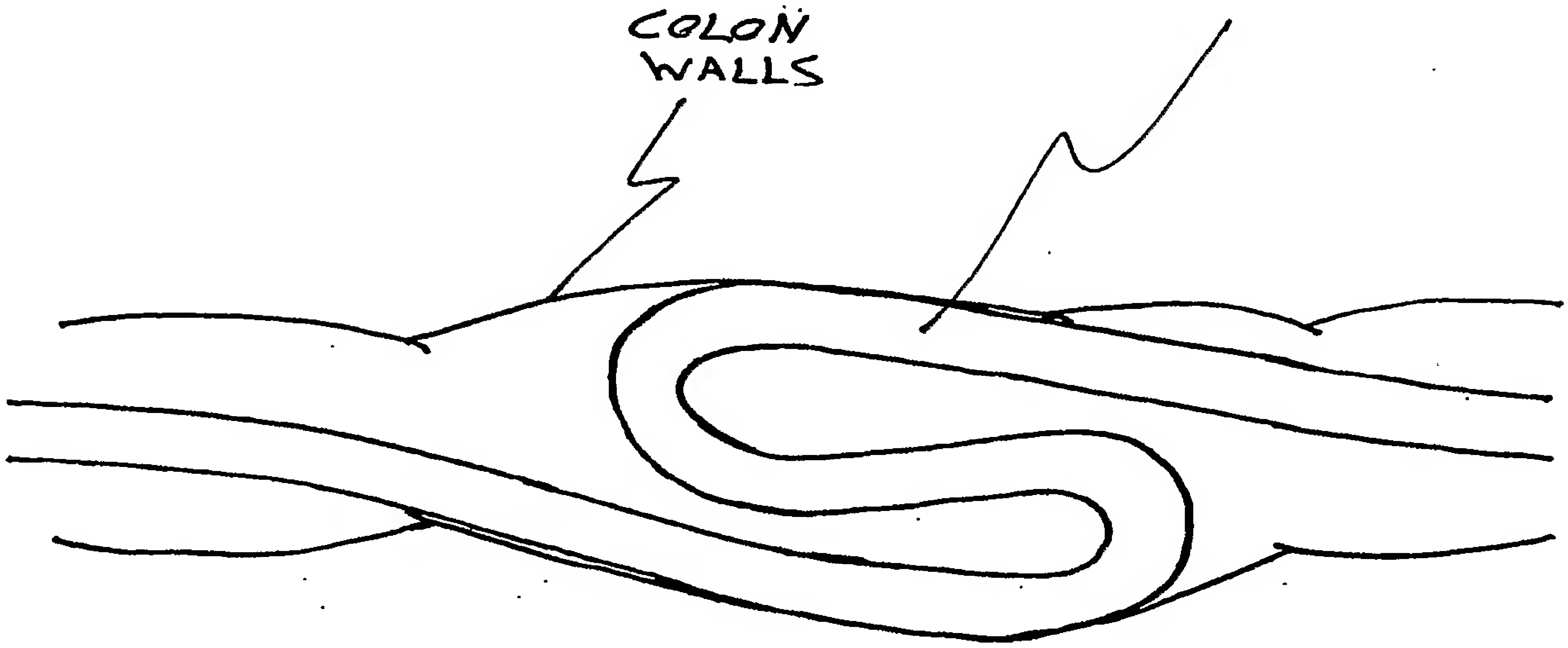
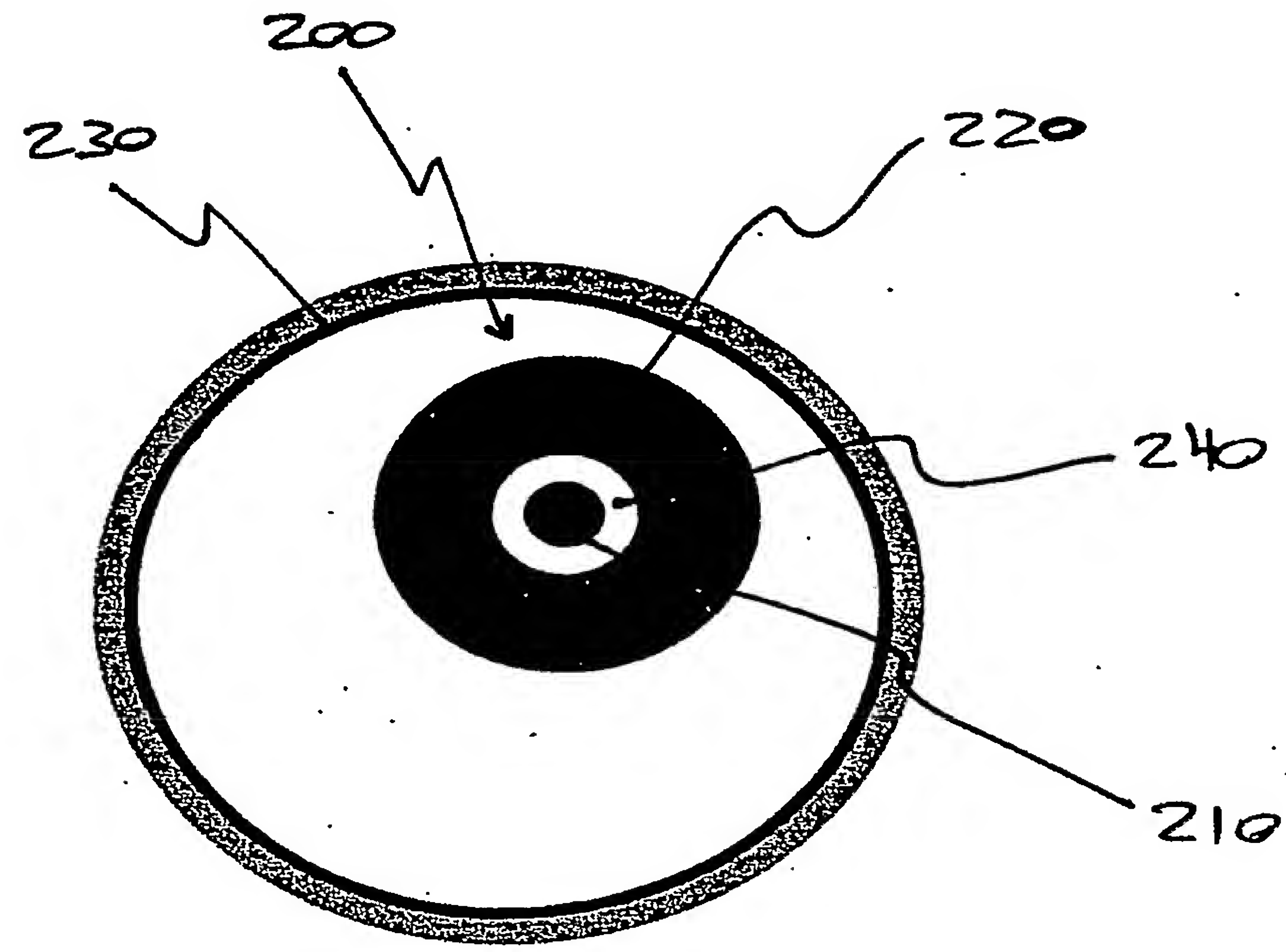


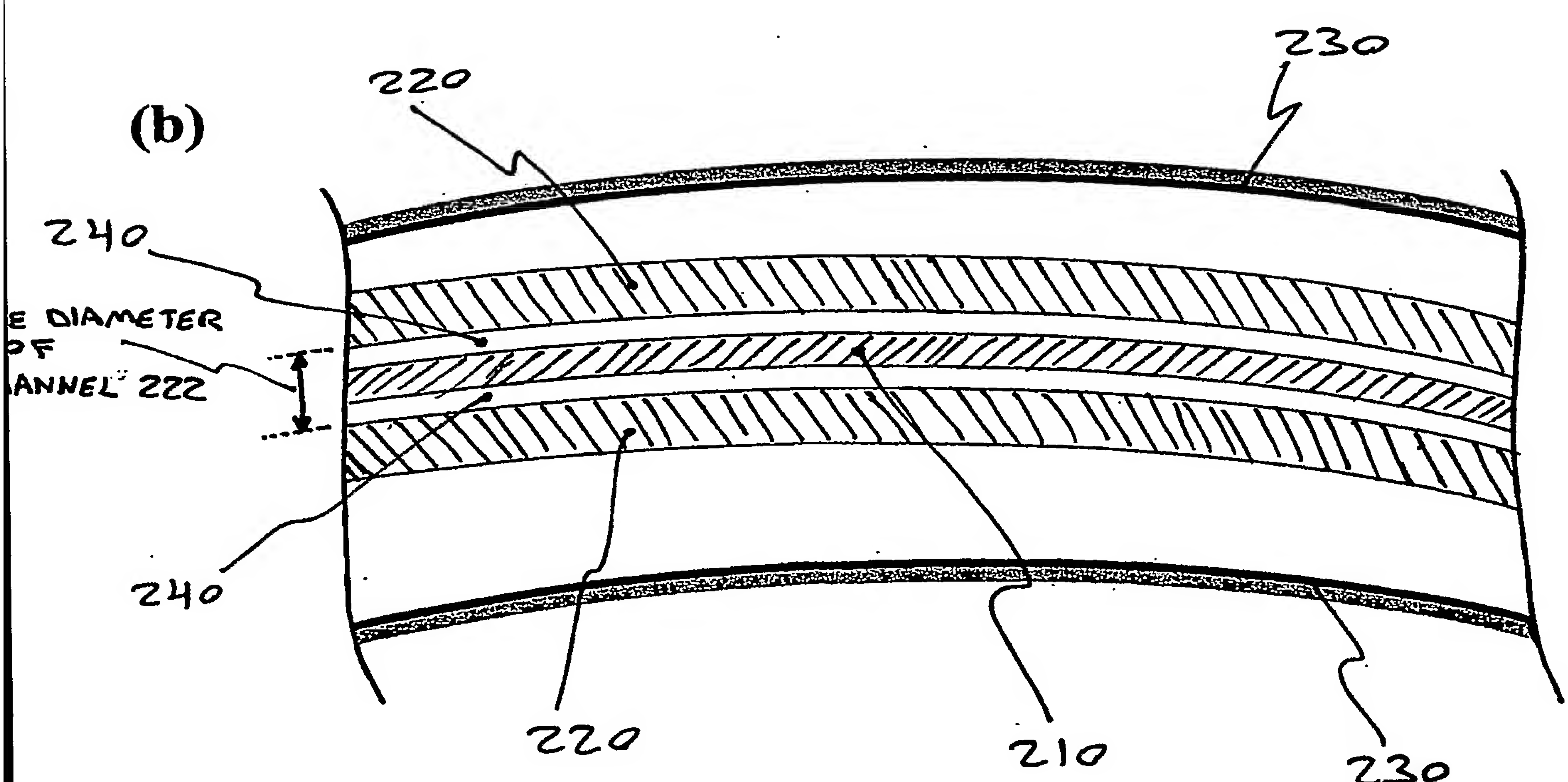
Fig.20:

(a)



200
230
220
240
210

(b)



220
230
240
E DIAMETER
OF
ANNEL 222
240
220
210
230

Fig.21:

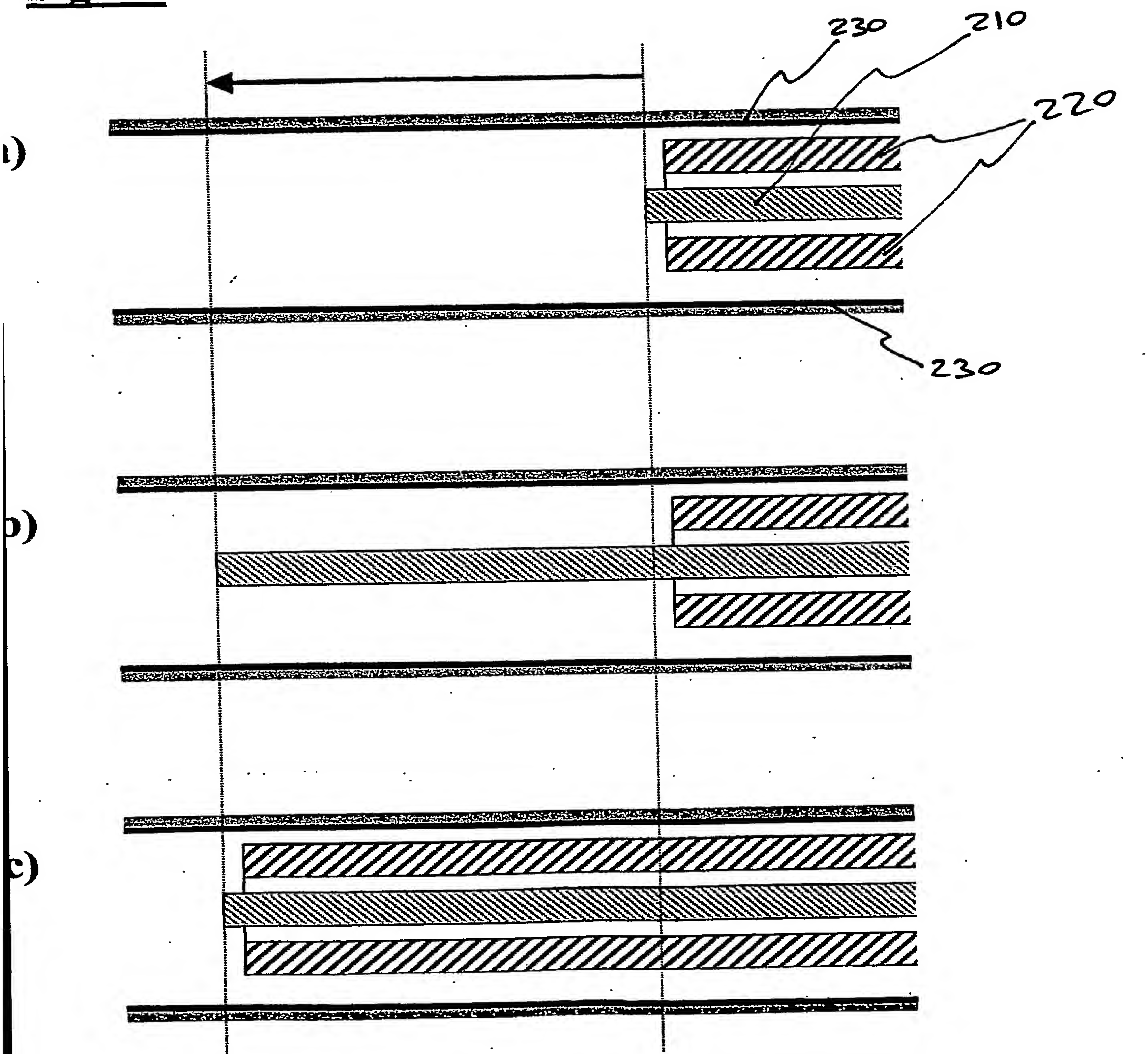


Fig.22:

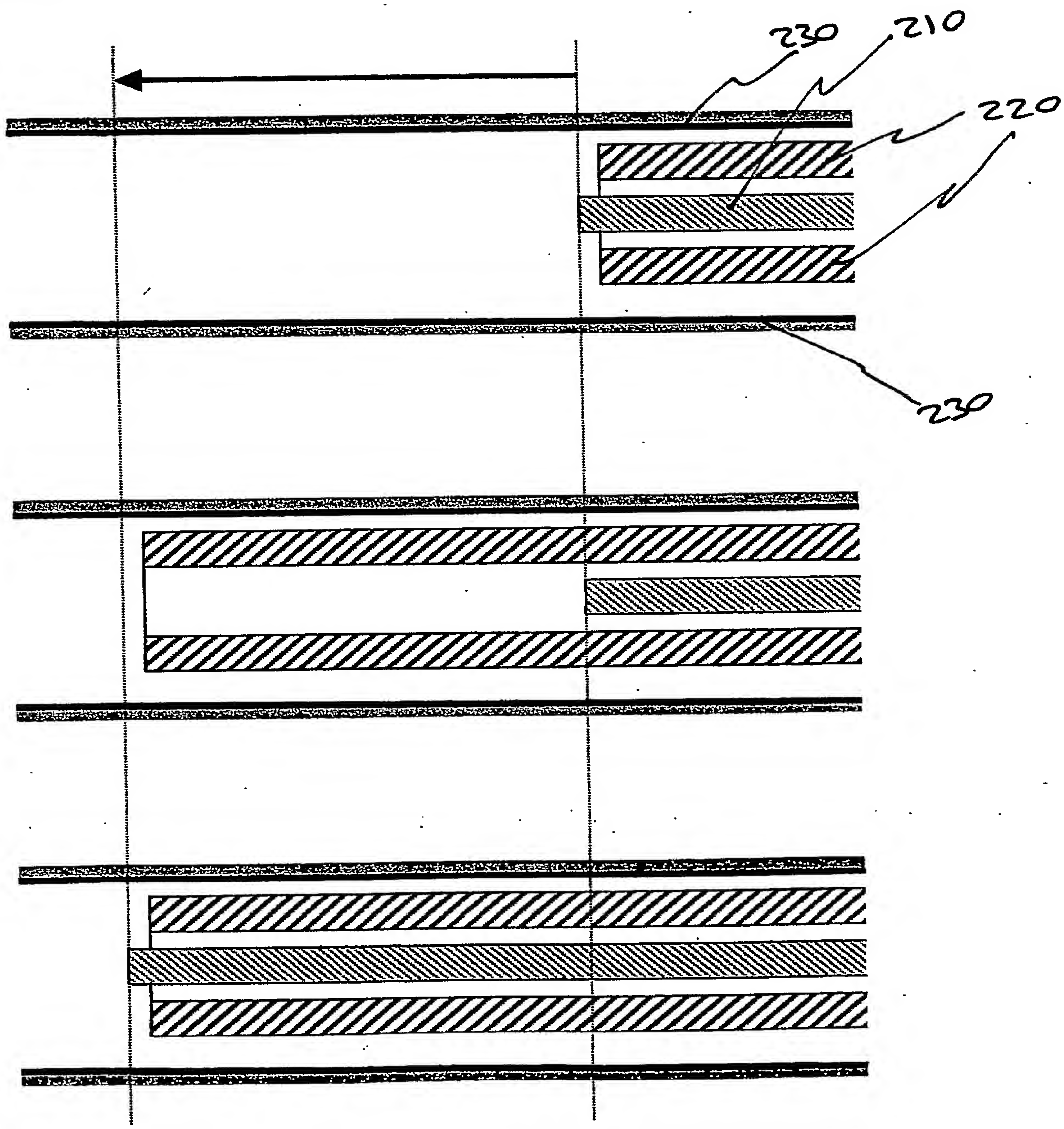


Fig.23:

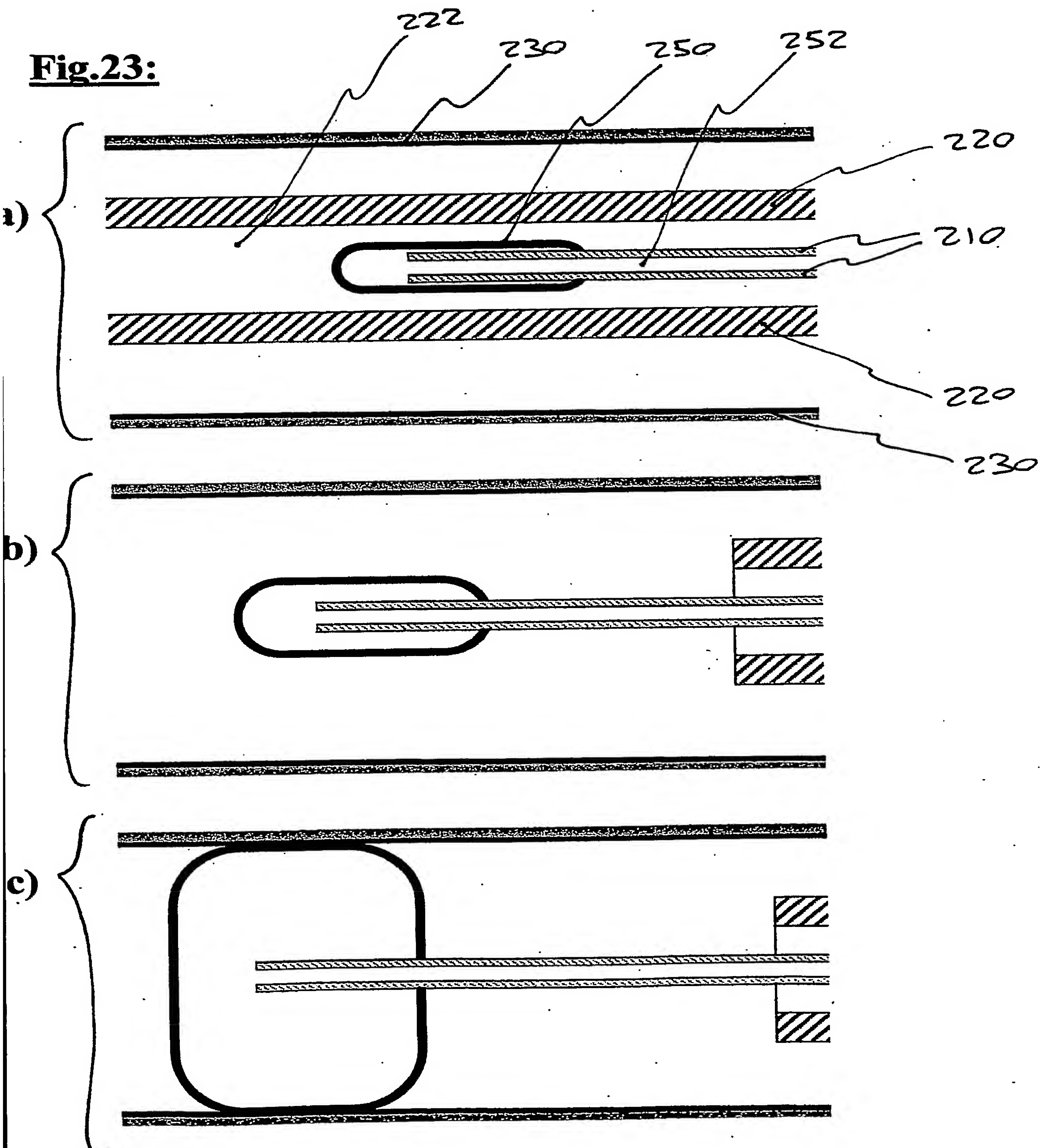
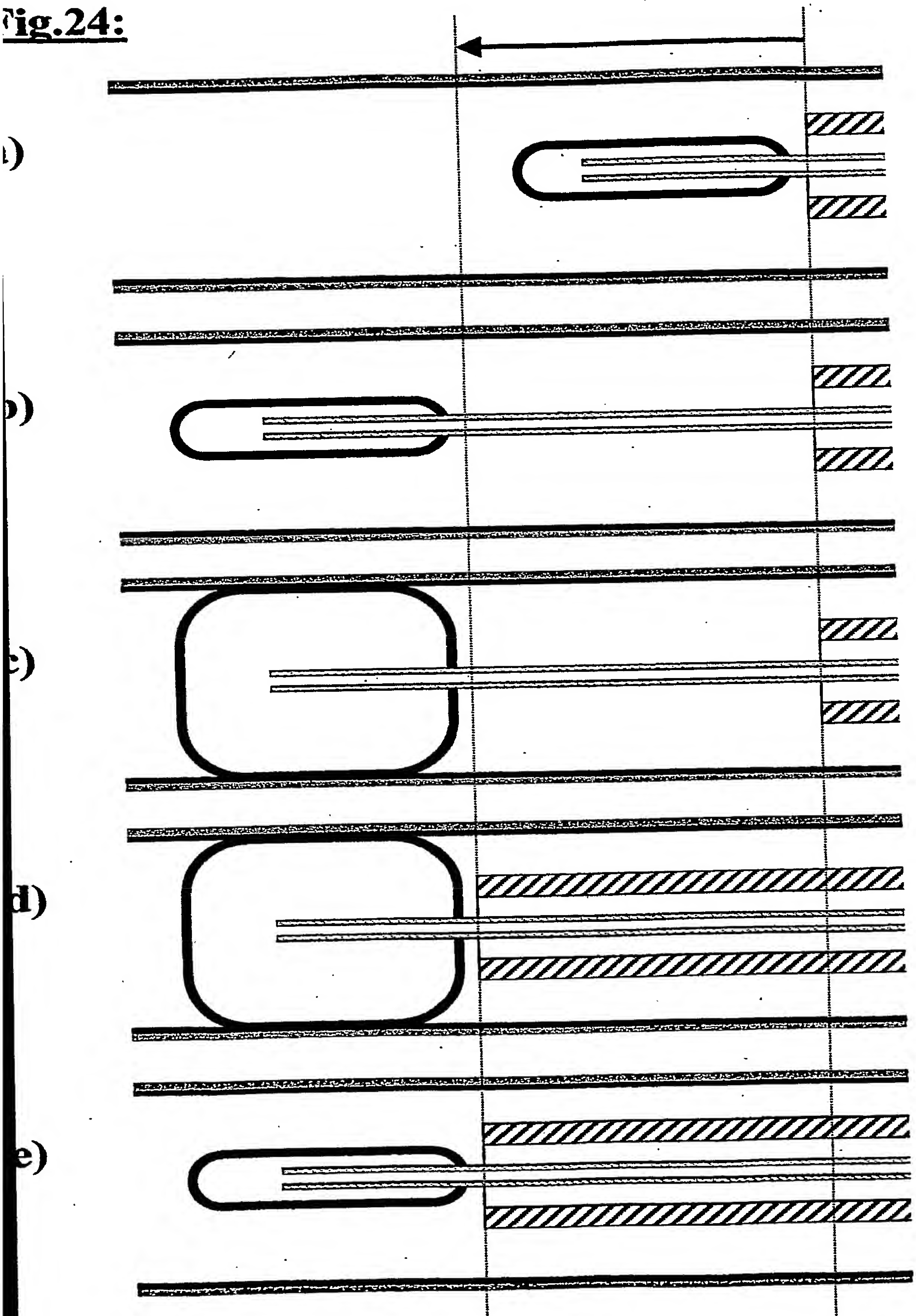


Fig.24:



ig.25:

a)

b)

(c)

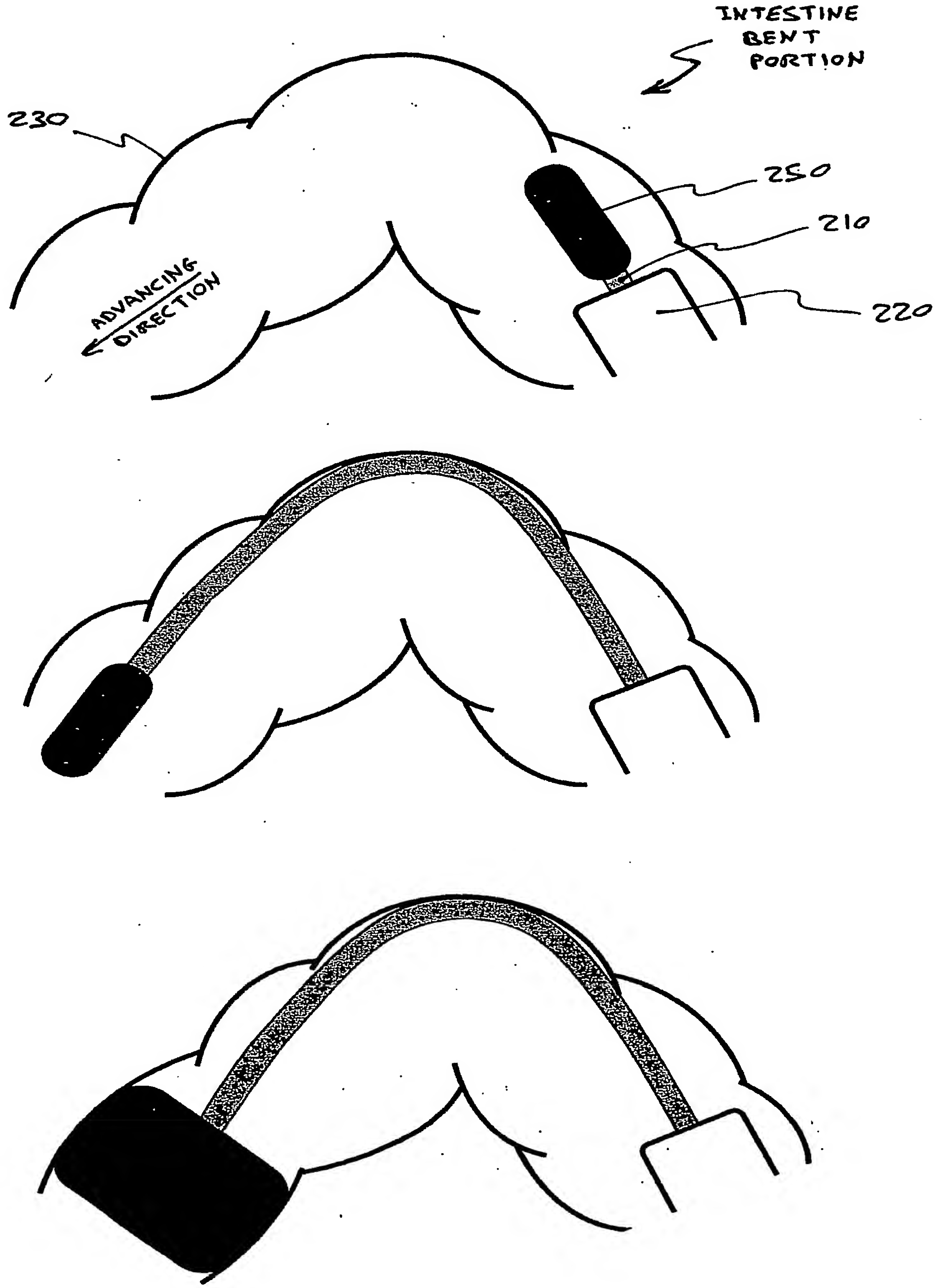
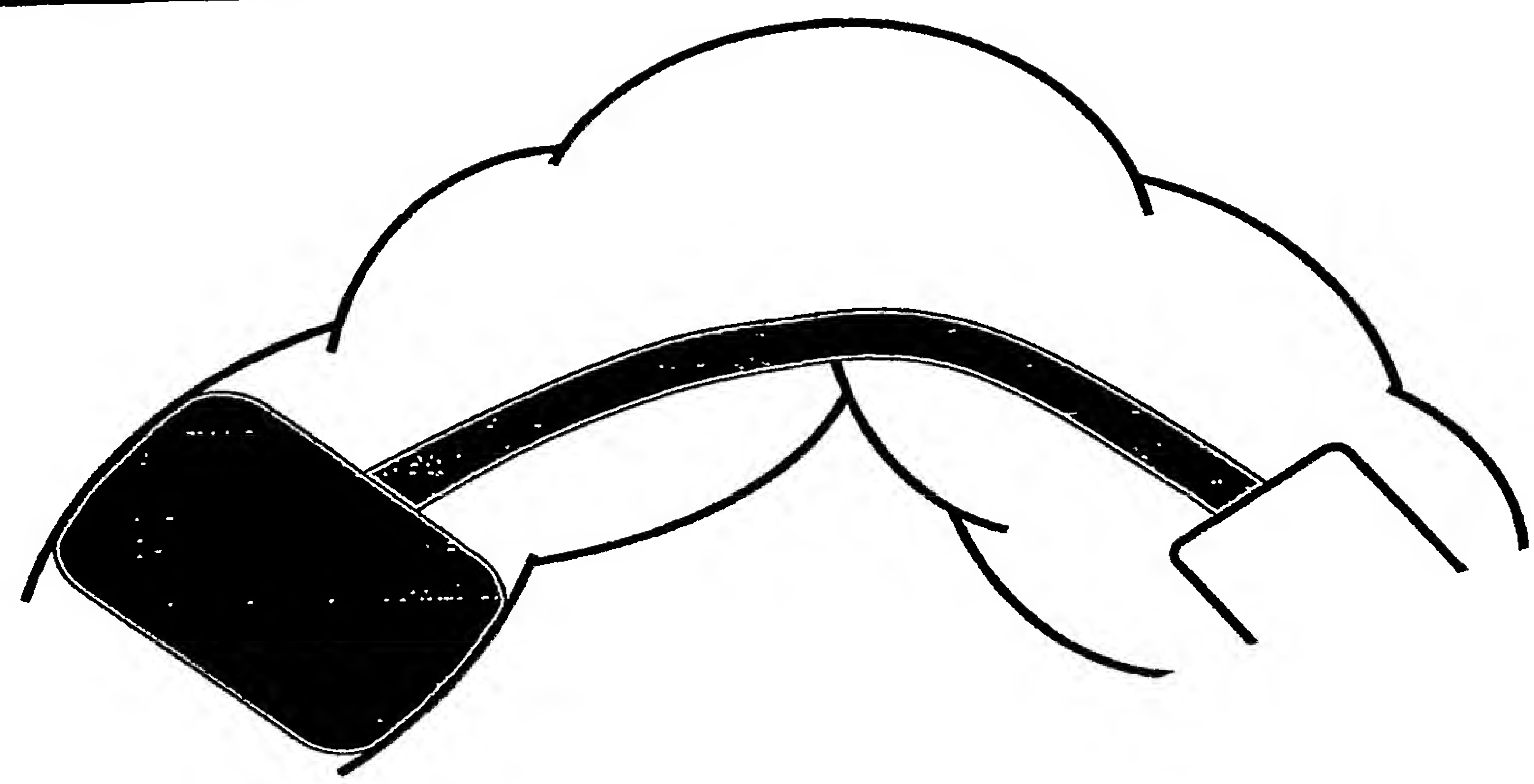

INTESTINE
BENT
PORTION
230
250
210
220
ADVANCING
DIRECTION

Fig.25 – continue:

(d)



(e)

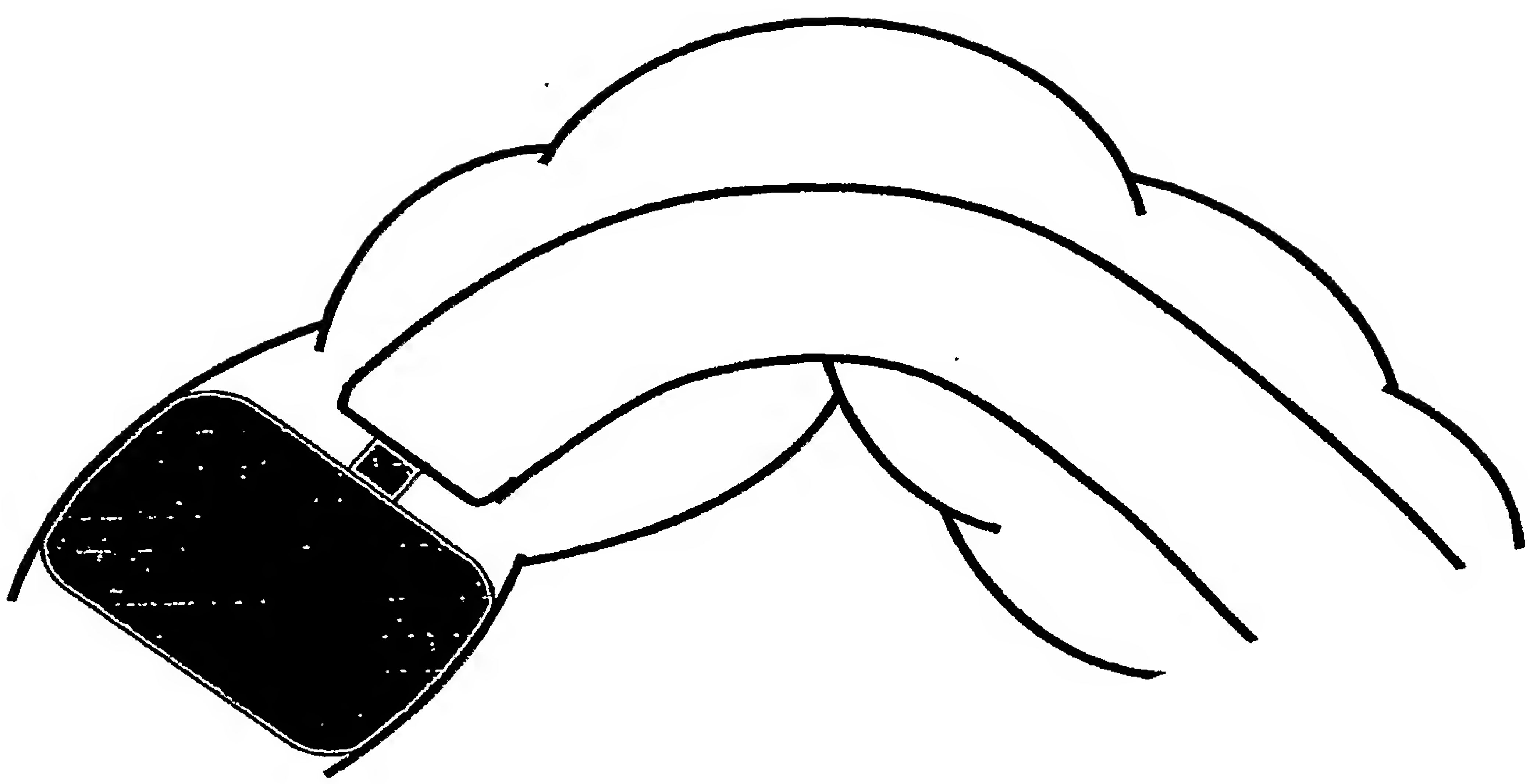
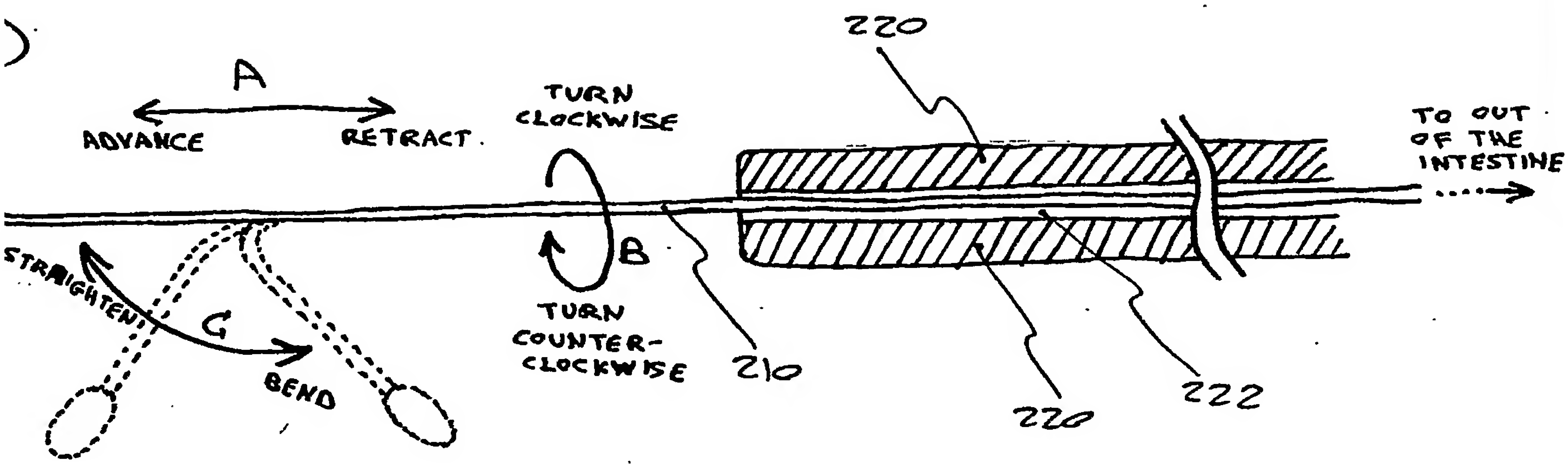
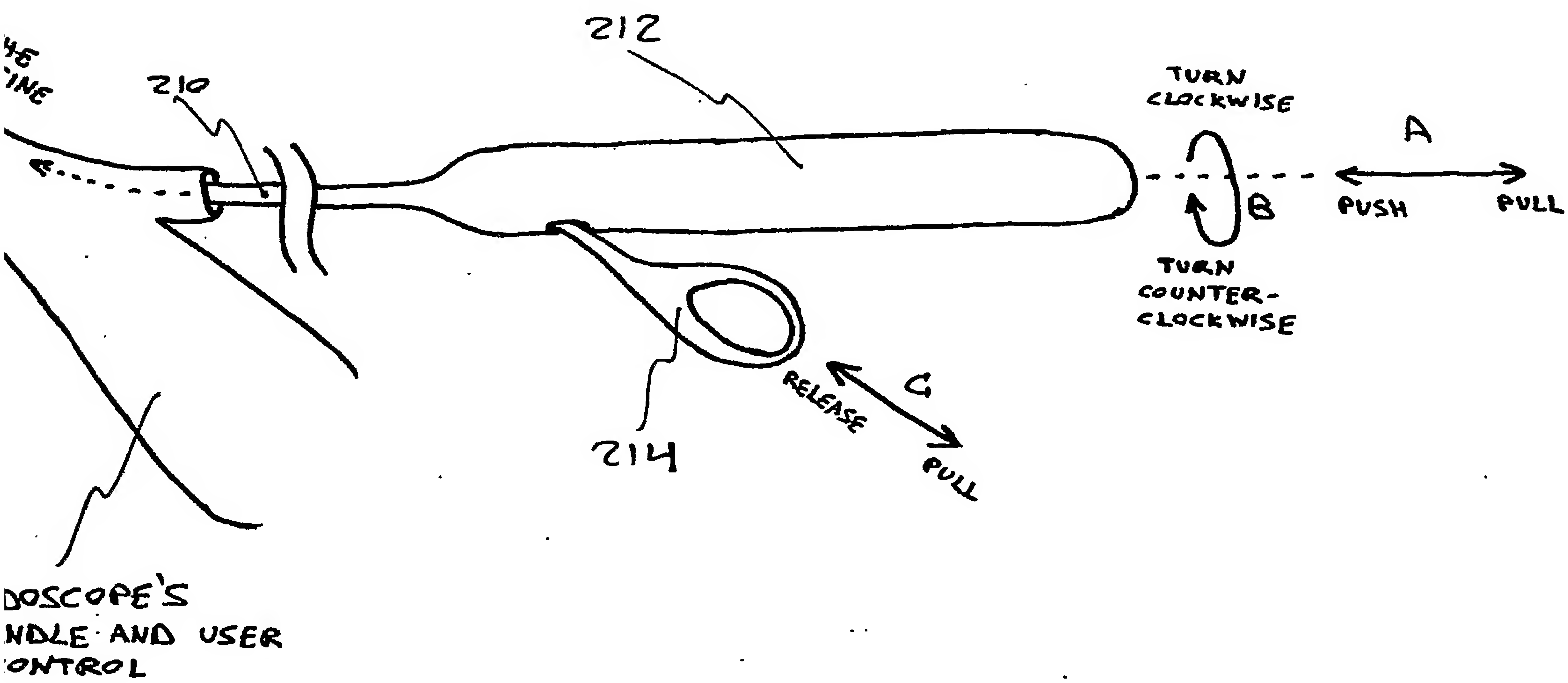


Fig. 26 :



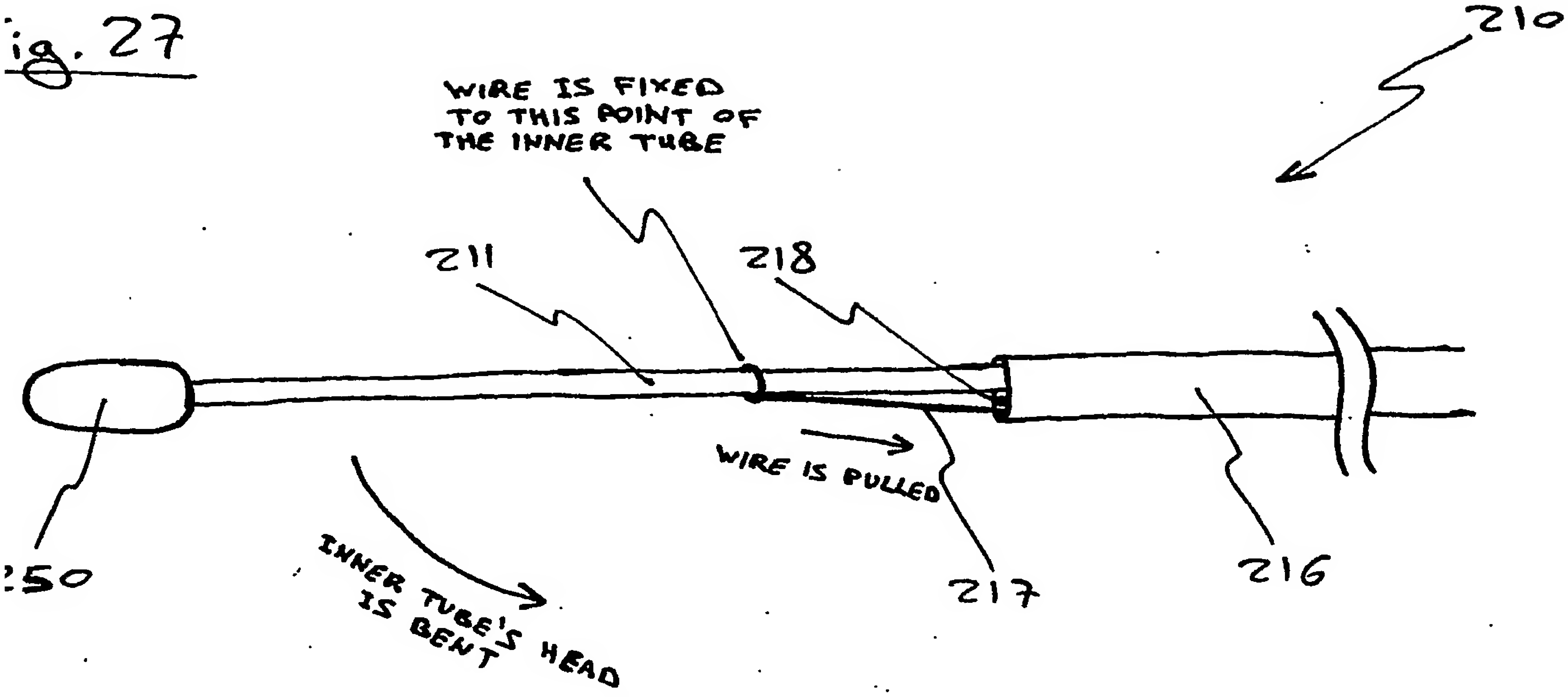
A
ADVANCE
RETRACT
TURN CLOCKWISE
B
TURN COUNTER-CLOCKWISE
220
TO OUT OF THE INTESTINE
STRAIGHTEN
C
BEND
210
220
222

(b)



212
210
TURN CLOCKWISE
A
PUSH
PULL
B
TURN COUNTER-CLOCKWISE
RELEASE
C
PULL
214
DOSCOPE'S
NDLE AND USER
ONTROL

ig. 27



210
WIRE IS FIXED TO THIS POINT OF THE INNER TUBE
211
218
WIRE IS PULLED
250
INNER TUBE'S HEAD IS BENT
217
216